

Health Policy Update – November 2, 2021

Network Advocates Meet with Congressional Lawmakers



Texas Oncology's Dr. Steve Paulson and Dr. Debra Patt traveled to Washington, DC last week to meet with members of Congress and advocate for community oncology.

Drs. Paulson and Patt had productive meetings with Senator Todd Young (R-IN), Representatives Larry Bucshon, MD (R-IN), Ronny Jackson, MD (R-TX), Kurt Schrader (D-OR) as well as with the offices of Senator John Cornyn (R-TX) and Rep. Dan Crenshaw (R-TX). Most of the day's discussions centered on the proposed cuts to Medicare reimbursement, concerns with prior authorization and step therapy, CMMI models, and staffing shortages.

Lawmakers Make Headway on Reconciliation and Infrastructure Bills

Negotiations among Congressional Democrats continue to move forward last week and lawmakers remain hopeful that Congress will soon vote on the reconciliation bill that comprises much of President Biden's "Build Back Better" agenda – which in turn unlocks a way forward for the bipartisan infrastructure bill that passed the Senate this summer to also pass the House.

As of Friday, Democrats appear to be closer to a deal on both bills after the White House unveiled a revised framework for the reconciliation bill in response to calls from moderate senators for the legislation to not spend more than \$1.5 trillion over 10 years – significantly less than the \$3.5 trillion sought by the White House and most House Democrats. The White House's framework mostly retains proposals such as the expanded Child Tax Credit, universal pre-Kindergarten, significant investments meant to combat climate change, and extended subsidies for insurance coverage purchased on Affordable Care Act-established exchanges. Other policies such as paid family leave, free universal community college, Medicaid expansion, and major investments in home healthcare and affordable housing were either dropped or significantly scaled back as was an ambitious proposal to add vision and dental benefits to Medicare.

Notably absent from the framework released on Friday was a provision to address prescription drug prices; however, lawmakers reportedly worked over the weekend to try and find agreement on the issue. Senate Finance Chairman Ron Wyden (D-OR) said Monday he is working on language that would include a scaled down version of drug price negotiation, a cap on price hikes above the rate of inflation, and an out-of-pocket max for Part D.

While Congressional leaders had originally aimed to pass the infrastructure bill ahead of Biden's departure to Rome for the G20 Summit, a vote on the measure was scrapped after progressive lawmakers threatened to oppose the measure unless and until more concrete details emerged on the reconciliation package. Instead, Congress passed a measure extending surface transportation programming through December 3, the same day government-wide funding is also set to expire.

To view the White House's reconciliation bill framework, [CLICK HERE](#).

Biden Meets Potential FDA Nominee Even as Some Senators Express Skepticism

On Friday, October 22, President Biden held a private meeting with Dr. Robert Califf, a former Food and Drug Administration (FDA) commissioner who is rumored to soon be nominated to return to the agency's top post.

Califf, a cardiologist, spent two years as deputy commissioner of medical products and tobacco office at the FDA and coordinated closely with then-Vice President Biden to launch the Cancer Moonshot Initiative. Califf also helped form the FDA's Oncology Center of Excellence. Nominated by President Obama to lead the agency, he sailed through the confirmation process on an 89-4 vote. After serving as FDA commissioner between January 2016 and January 2017, Califf worked at the Duke Clinical Research Institute and directed medical strategy and policy at Alphabet, Google's parent company.

However, some lawmakers and healthcare stakeholders have expressed opposition to Califf's potential nomination. Advocacy groups including Public Citizen and the Revolving Door Project expressed concern that Califf was too cozy with the pharmaceutical industry, a concern that Sen. Bernie Sanders (I-VT) expressed during Califf's confirmation hearing in 2016. In addition, Senators Joe Manchin (D-WV) and Richard Blumenthal (D-CT), who both voted against Califf in 2016, have again expressed their opposition to his nomination due to his approach towards regulating opioids. Given Democrat's razor-thin majority in the Senate, Califf would likely need Republican votes if President Biden officially nominates him to lead FDA.

The FDA has been overseen by acting commissioner Janet Woodcock for the past 10 months. Under federal law, President Biden has until November 15 to nominate Woodcock or select an alternative leader for the agency.

CMMI Aims to Streamline Payment Models, Improve Health Equity with New Strategic Plan

On October 20, the Center for Medicare and Medicaid Innovation (CMMI) issued a strategic plan with the stated goal of achieving equitable outcomes through high-quality, affordable, person-centered care. In unveiling the new plan, Biden Administration officials said there would be fewer

models moving forward to prevent overlap and confusion among healthcare providers. Moreover, the agency will help encourage more providers to participate in future models by providing more actionable data and payment flexibility.

According to CMMI's white paper on the strategic refresh, the agency will approach new models with 5 key objectives: drive accountable care, advance health equity, support innovation, address affordability, and partner to achieve system transformation.

While the white paper does not provide details on new models, it does note that the Innovation Center will prioritize models that test ways to lower beneficiary and program spending on drugs and incentive the use of biosimilar and generic drugs, including testing innovative payment approaches for Medicare Part B drugs or total cost of care models that could include both Part B and Part D drugs. It also highlights the Radiation Oncology Model as one testing site neutral payments.

To read more about CMMI's strategic refresh, [CLICK HERE](#) and [HERE](#).

To read the CMS white paper, [CLICK HERE](#).

Senator Wyden Urges CMS Review of Pharmacy Closures and Role of DIR Fees

On October 20, Senator Ron Wyden (D-OR), Chairman of the Senate Finance Committee, sent a letter to the Centers for Medicare & Medicaid Services (CMS) urging review of pharmacy closures nationwide in the last five years to examine the role fees imposed by Medicare Part D plans and pharmacy benefit managers (PBMs) play in recent closures.

Referencing the recent closure of 56 pharmacies in his home state of Oregon and the Northwest, Senator Wyden questions the negative impacts direct and indirect remuneration (DIR) fees imposed by Part D plans and PBMs are having on pharmacies' ability to remain stable and operational. His letter also stresses the risks these fees inflict on rural pharmacies, in particular, that are essential to their communities in providing patient education, disease management and vaccine administration.

"These fees do nothing to lower the amount Medicare beneficiaries must pay for their drugs each time they fill a prescription and seemingly serve only to pad plan and PBM profits," Senator Wyden wrote.

Senator Wyden's letter also highlighted the CMS report to Congress in June that stated Part D plans and PBMs increased pharmacy DIR fees by an "astounding" 91,500 percent from 2010 to 2019 and that fees doubled from 2018 to 2020.

To read Senator Wyden's letter, [CLICK HERE](#).

Bill Streamlining MA Prior Authorization Gains House Majority Support as Companion Bill Introduced in the Senate

Last week it was reported that the Improving Seniors' Timely Access to Care Act of 2021, a bipartisan bill meant to curb insurer use of prior authorization in Medicare Advantage plans, had

secured the support of a majority of House members. The news comes as a companion bill was recently introduced in the Senate.

If enacted, the bill would establish an electronic prior authorization process, establish a process for real-time decisions for items and services that are routinely approved, and order MA plans to report on their use of prior authorization— improving communication between MA plans, providers, and patients.

Representatives Larry Bucshon, MD (R-IN), Suzan DelBene (D-WA), Mike Kelly (R-PA), and Ami Bera, MD (D-CA) initially introduced the bill in April of this year and have secured the support of 227 co-sponsors as of October 8, 2021. Senators Roger Marshall, MD (R-KS), Kyrsten Sinema (D-AZ), and John Thune (R-SD) introduced a companion bill in the Senate on October 20, 2021.

A broad range of groups has come out in support of the Improving Seniors' Timely Access to Care Act including the American Medical Association, the American Society for Radiation Oncology, the American Hospital Association, and others. With nearly 80% of Medicare Advantage enrollees subject to unnecessary delays because of prior authorization and 30% of physicians reporting prior authorization has led to a serious adverse event for one of their patients, the bill aims to modernize the way MA plans use prior authorization and lessen the administrative burden on physicians.

To learn more about the House bill, [CLICK HERE](#).

To learn more about the Senate bill, [CLICK HERE](#).