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Health Policy Update – September 21, 2021

Medicare Negotiation Proposal Narrowly Defeated in One Committee; Approved by Another

Lawmakers' efforts to tackle prescription drug prices took center stage last week as the House of Representatives continued work on its expansive $3.5 trillion reconciliation package, known as the Build Back Better Act. In the Energy & Commerce (E&C) Committee, a provision that would allow Medicare to negotiate prescription drug prices narrowly failed to advance after three Democratic members, Reps. Scott Peters (D-CA), Kurt Schrader (D-OR), and Kathleen Rice (D-NY) voted with Republicans to defeat the measure. However, the Ways & Means (W&M) Committee subsequently approved the provision during its own mark-up session – setting the stage for a future debate over the issue on the House floor. Democrats can only lose 3 votes in the chamber, leaving little flexibility to accommodate defections. It is not immediately clear whether the three E&C members would vote against the entire reconciliation package if it includes the drug pricing provisions they opposed in committee.

Medicare negotiation also faces a difficult hurdle in the Senate where several moderate Democrats have expressed concern with the proposal. The Senate Finance Committee is reportedly working on its own drug pricing bill though the details have yet to be disclosed. While the House is expected to advance the reconciliation bill through both the Budget and Rules Committees in the coming weeks, clearing the way for a floor vote, the exact timing is unclear given the slate of other time-sensitive measures pending before Congress.

For their part, proponents of Medicare negotiation were bolstered by the HHS' release of a prescription drug pricing plan that threw the administration's full weight behind the proposal. The plan, which was required by an Executive Order from President Biden, also calls for caps on beneficiary spending in Medicare Part D, new rebates on manufacturers increasing drug prices faster than inflation and measures to spur faster development of generics such as banning "pay for delay" agreements. Notably, it does not take a firm position on the use of so-called "march-in rights" to compel manufacturers to license generic version of their drugs nor does it mention tying U.S. drug prices to international rates.

To view the E&C Committee reconciliation markup, CLICK HERE.

To view the W&M Committee reconciliation markup, CLICK HERE.

To view the White House Prescription Drug Pricing Plan, CLICK HERE.

The Network Submits Physician Fee Schedule Comments

Last week, The Network submitted comments to CMS concerning the 2022 Physician Fee Schedule (PFS) proposed rule. The Network's comments urged the agency to work with Congress to address the imminent payment cuts posed by the lapse of the temporary conversion factor increase, COVID-19 sequestration relief, and S-PAYGO for CY 2022. If the proposed payment reductions of more than -7% are finalized and go into effect as proposed, The Network warns that they would threaten patients' access to cancer care. The Network praised CMS for taking bold action to help providers during the COVID-19 public health emergency, including extending financial relief and streamlining regulations, but warned that implementing the proposed cuts would "forfeit the hard-fought progress gained against this pandemic."

In related news, a bipartisan group of 75 House lawmakers led by Representatives Bobby Rush (D-IL) and Gus Bilirakis (R-FL) sent a letter to CMS urging the agency not to finalize a portion of the proposed rule that would cut Medicare reimbursement rates by up to 20% for specialty providers – including oncologists. The cuts are a consequence of CMS' proposed changes to update clinical labor pricing, which has not been widely updated since 2002. Though the updates reflect across-the-board increases for nearly all labor categories, budget neutrality requirements within the fee schedule yield net cuts for some specialties. In their letter, the Members warned that these cuts undermine efforts to achieve health equity and will force specialty providers to close, leading to even worse health impacts for vulnerable groups.

To view The Network's PFS comment letter, CLICK HERE.

To view the Rush-Bilirakis letter, CLICK HERE.

The Network Responds to Radiation Oncology Model Proposed Rule

On September 17, The Network submitted comments to CMS regarding the Radiation Oncology (RO) Model included in the Hospital Outpatient Prospective Payment System Proposed Rule. The comments continued to advocate for changes that would result in more meaningful practice transformation and warned CMS about the combined impact of cuts in the RO Model, the CY 2022 PFS proposed rule, and the COVID-19 pandemic on freestanding radiation oncology practices.

The Network specifically urged CMS to adopt the following Model recommendations:

- Reduce the discount factor to 3.0% for both the Professional Component and the Technical Component;
- Modify the trend factor to prevent additional downside risk and provide payment stability;
- Provide the 5% APM incentive bonus for technical payments to freestanding practices;
- Delay Clinical Data Element reporting for two years; and
- Provide additional payment methodology data and billing guidance.

The American Society for Radiation Oncology (ASTRO) also submitted comments on the proposed rule, urging CMS to make several modifications to the RO Model, including reducing the Model's discount factor to 3% or less, establishing a COVID-19 adjustment, eliminating barriers to Advanced

APM status, and establishing a “Health Equity Achievement in Radiation Therapy” payment.

To read The Network’s comment letter on the RO Model, CLICK HERE.

To read ASTRO’s RO comment letter, CLICK HERE.

Biden Administration Issues Vaccine Mandates, Unveils New Pandemic Strategy

In a speech on September 9, President Biden announced sweeping new federal policies designed to increase the number of Americans who are vaccinated against COVID-19. The six-point “Path Out of the Pandemic” plan detailed plans to prevent the spread of COVID-19, while keeping schools and businesses open including increasing testing, requiring masking, and improving care for those infected with the virus.

Most notably, President Biden’s plan outlined concrete measures to increase the number of COVID-19 vaccinations. For instance, the Occupational Safety and Health Administration (OSHA) is developing a new rule that will require all employers with more than 100 employees to ensure their staffs are all vaccinated or tested on a weekly basis - impacting over 80 million people working in the private sector. The plan would also require all federal workers and contractors to receive vaccinations as a condition of employment with no option for testing. Moreover, CMS is requiring COVID-19 vaccinations for over 17 million health care workers at Medicare and Medicaid participating hospitals and other health care settings such as home health agencies and ambulatory surgical centers.

On Friday, an FDA advisory panel rejected a proposal to administer Pfizer/BioNTech vaccine boosters to the general public. Instead, the body supported a modified policy recommending individuals over the age of 65 and/or those with underlying health conditions receive a third-shot booster. It is not yet clear how the Biden Administration may modify its previously announced endorsement of COVID-19 booster shots for the general public.

To view President Biden’s “Path Out of The Pandemic” plan, CLICK HERE.

HHS to Provide Additional $25.5 billion in COVID-19 Provider Relief

The Department of Health and Human Services announced last week that providers will soon be able to apply for additional pandemic relief grants. HHS authorized $25.5 billion for small and rural healthcare providers who have experienced significant pandemic-related financial stress between July 1, 2020, and March 31, 2021.

HHS Secretary Xavier Becerra said in a news release that the distribution of funding will be equitable and ensure that providers in the most vulnerable communities will receive much-needed support. The funds will include $17 billion for small providers serving vulnerable communities and $8.5 billion in American Rescue Plan Act grants for rural providers.

The fourth phase of Provider Relief Fund grants will have the same deadlines to use funding; however, HHS will allow a 60-day grace period to comply with the Provider Relief Fund reporting requirements to offset the impact of the recent delta variant surge and natural disasters. Recipients of the funds must also notify HHS if they have merged with or acquired another healthcare provider during the grant period.

To view HHS' announcement about the additional funding, CLICK HERE.

Report: 340B Hospitals Profiting from Cancer Drugs

A new report commissioned by the Community Oncology Alliance (COA) revealed that non-profit 340B hospitals have been increasing revenue by marking up oncology drug prices to patients and private insurers.

The report reviewed 52,180 individual hospital-reported prices for 59 different oncology drugs with the highest Medicare expenditures in 2019. It found that 340B hospitals charge patients an average of 3.8 times more than their acquisition price. One drug used to treat anemia caused by chemotherapy was priced 11 times higher than its cost to the hospital.

The report also found that 340B hospitals overwhelmingly have not complied with federal hospital transparency regulations that went into effect his year with only 11% publishing all the required data on drug pricing.

The American Hospital Association (AHA) responded to the COA report arguing it, "tries to obfuscate the issue of sky-rocketing drug prices by choosing to blame hospitals rather than drug companies who set the prices…" The response asserts the 340B program is working as Congress intended it and that hospitals are left with reimbursement shortfalls for a large portion of services provided under Medicare and Medicaid.

To read the 340B report, CLICK HERE.

To read the AHA response, CLICK HERE.