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Health Policy Update – September 9, 2020

The Network Shares Experience with Oncology Care Model Following Release of Latest Evaluation Report

On August 27, The Network sent a letter to Center for Medicare and Medicaid Innovation (CMMI) Director Brad Smith responding to the latest evaluation report that analyzed the first three performance periods of the Oncology Care Model (OCM).

The evaluation report, which was issued in July, focused on Performance Periods (PP)1-3 of the 6-year program and estimated that the OCM resulted in $154 million in net losses to the Medicare program after accounting for Monthly Enhanced Oncology Services (MEOS) and Performance-Based Payments (PBP). The report also suggested that, during the first three performance periods, the OCM had no impact on hospitalizations, minimal impact on emergency department visits, and no impact on hospice utilization.

“In contrast to the report, our interpretation of OCM data among Network practices points to remarkable model success in driving practice change, improving patient care, and lowering costs,” the letter read. “The Network appreciates CMS’ commitment to stakeholder input and encourages the agency to consider our perspective as it contemplates OCM improvements and determines the design of future oncology models, such as the Oncology Care First (OCF) Model.”

The Network’s letter provided additional data to contextualize its findings, highlighting the fact that the report likely did not have the opportunity to analyze enough performance data to capture positive trends within the OCM. According to The Network’s data, the model did not begin generating notable positive results until PP3 – once practices developed familiarity with the OCM and implemented a number of practice transformation initiatives.

“The shift to value-based care, and specifically episode-based cancer care, takes time. The OCM demanded fundamental practice transformation, including new financial and infrastructure investments, along with a significant shift in the delivery of patient care, including the scope and coordination of the care team,” the letter continued. “Because of this, across The Network we did not begin to see meaningful changes in key OCM metrics until PP3. If our results are transferable to OCM practices as a whole, future evaluations will reflect a marked shift beginning in PP3.”

In particular, the letter noted that based on data through PP5, The Network’s OCM-participating practices saved the Medicare program $78 million. Its data also suggests Network practices reduced hospitalizations and emergency department (ED) visits and increased hospice utilization relative to PP1.

To view The Network’s letter, CLICK HERE.

To view the evaluation report on PP1-PP3 of the OCM, CLICK HERE.

To read CMS' perspective on the evaluation report, CLICK HERE.

Senate Tees Up Vote on "Skinny" COVID-19 Relief Package

On September 8, Senate Majority Leader Mitch McConnell (R-KY) announced the chamber would vote on a targeted COVID-19 relief bill as soon as this week. The announcement comes after weeks of partisan disagreement over the scope, cost, and necessity of additional legislative action. While the House passed a $3 trillion package in May, known as the HEROES Act, the Republican-led Senate argued the bill was too large and expensive. Senate Republicans proposed a $1 trillion alternative in July that was met with resistance by House and Senate Democrats.
Amidst the impasse on bipartisan, bicameral negotiations, Leader McConnell said Tuesday, "Working families must not suffer more than necessary because Democrat leaders think citizens' pain may help their political fortunes. Congress can, should, and must do more to help. The Senate will vote and the American people will be watching." The move was quickly met with resistance by House Speaker Nancy Pelosi (D-CA) and Senate Minority Leader Chuck Schumer (D-NY) who called the bill "emaciated" and "headed nowhere."

The skinny coronavirus relief bill, titled the Delivering Immediate Relief to America's Families, Schools and Small Businesses Act, includes provisions to extend the Payroll Protection Program, enhanced unemployment benefits, and additional funding for Schools and childcare centers. It would also include liability protections and funding for the U.S. Postal Service. While there is no deadline to pass another round of COVID-19 relief, annual government funding runs out on September 30, preceding a scheduled congressional recess in the weeks leading up to the November elections.

To read the statement from Senate Majority Leader McConnell, CLICK HERE.

To read the statement from Speaker Pelosi and Senate Minority Leader Schumer, CLICK HERE.

To read the text of the Delivering Immediate Relief to America's Families, Schools and Small Businesses Act, CLICK HERE.

Status of Administration's Most Favored-Nation Plan Remains in Limbo

On July 24, President Donald Trump signed four executive orders (EO) related to prescription drug prices. All four orders require regulatory action by the Administration before they can be implemented. While three of the four executive orders (EO) were released publicly, the Administration has yet to make public the EO pertaining to the Most Favored Nation (MFN) drug pricing proposal, which would tie Medicare Part B drug prices to an international benchmark.

The President initially gave pharmaceutical manufacturers (PhRMA) 30 days – until August 25th – to propose an alternative to the MFN proposal. That date has come and gone without the finalization of the MFN executive order or the announcement of an alternative approach.

There have been multiple reports that PhRMA proposed a counteroffer to the Administration, which may be subject to ongoing negotiation, though details remain elusive. The rumored proposal broadly outlined a two-phase alternative to MFN with short-term and long-term goals. The short-term plan is reported to include 'market-based' adjustment discounts whereby drug makers voluntarily provide drug discounts in the commercial market by reducing average sales prices (ASP) as much as 10%. The long-term plan could include a number of reforms to Medicare Part B, including a competitive acquisition program-type model, which The Network is closely monitoring for impact to providers.

Related, on September 1, 46brooklyn – a non-profit corporation whose purpose is to improve the accessibility and usability of U.S. drug pricing data – released an analysis looking at drug pricing databases in Australia and the United States, concluding that the MFN approach may not work in reducing drug costs in some instances because drug companies could find ways to sell drugs in the U.S. that aren't available abroad and therefore don't have an international reference price.

To read about PhRMA's reported counteroffer on MFN, CLICK HERE.

To read the 46Brooklyn report, CLICK HERE.

New Analysis Estimates Costs and Fiscal Impact of Biden Campaign's Healthcare Plan

A report from the Committee for a Responsible Federal Budget (CRFB), a non-partisan research group that aims to educate the public on issues with significant fiscal policy impact, reviewed the Biden presidential campaign's healthcare plan.

Biden's plan proposes to build on and expand the Affordable Care Act (ACA) by increasing marketplace subsidies, adopting auto-enrollment, and offering a new public option available to those in the individual market or with employer-sponsored health coverage. The proposal would also lower the Medicare age from 65 to 60, establish a new long-term care tax credit, increase funding for rural and mental health services, enact surprise billing reform, and allow Medicare to negotiate the cost of prescription drugs.

The CRFB analysis found that the Biden plan would extend healthcare coverage to an additional 15-20 million people who are currently uninsured. To evaluate the fiscal impact of the plan, CRFB broke its estimate into three scenarios; low, central, and high. According to the central estimate, Biden's plan would add $850 billion to the national deficit over 10 years. It would save $250 billion under the low-cost estimate and add $1.35 trillion to deficits under the high-cost estimate.

Further, the plan is expected to reduce national health expenditures by as much as 3% or increase them by as much as 1% depending on the estimate used. Under the central estimate, total costs will fall by 1%, with premiums and out-of-pocket costs declining slightly more than public costs increase.

To view the CRFB analysis, CLICK HERE.

CMS Proposes Pathway for Coverage of “Breakthrough” Devices & Technologies

On August 31, the Centers for Medicare & Medicaid Services (CMS) released a new proposed rule outlining timely coverage for innovative technologies and breakthrough devices. If finalized as written, the proposed rule would create a new Medicare coverage pathway, Medicare Coverage of Innovative Technology (MCIT), for FDA-designated breakthrough medical devices. The proposal would provide Medicare coverage of such devices on the same day it receives market authorization by the Food and Drug Administration (FDA). The proposed coverage would last for four years, allowing immediate access by patients. According to CMS, manufacturers would have all current coverage options available such as a National Coverage Determination (NCD), one or more Local Coverage Determinations (LCD), and claim-by-claim decisions once the MCIT coverage ends after four years.

The MCIT proposal is based on President Trump’s Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors (EO 13890), which instructed CMS to clarify coverage standards and consider market-based policies in order to streamline coverage, coding, and payment for innovative technologies. Coverage under MCIT would only be available for FDA-designated breakthrough devices (which include some diagnostic tests) that have subsequently been market authorized. CMS encouraged stakeholders to comment on the proposed rule. Comments are due November 2, 2020.

To read the CMS press release on the rule, CLICK HERE.

To read the proposed rule, CLICK HERE.

To read President Trump’s Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors (EO 13890), CLICK HERE.

Tensions Continue Among 340B Program Stakeholders

Two recent developments underscore the tension between pharmaceutical companies, pharmacies, and hospitals when it comes to the 340B Drug Pricing Program.

On August 21, the American Hospital Association (AHA) sent a letter to Sanofi urging the company not to require covered entities to submit contract pharmacy claims data every two weeks starting on October 1. AHA expressed concern that the short-notice requirements would be burdensome for hospitals and negatively impact their ability to serve vulnerable patients under the 340B program. The letter, which highlights the statutory, administrative, and ethical concerns AHA has over Sanofi’s policy, also expressed dismay that Sanofi had neither justified the need for this detailed reporting, nor did it demonstrate that it explored less burdensome ways to obtain it.

In a response letter sent on August 28, Sanofi denied that its policy ran afoul of federal law or imposed burdens on hospitals and pharmacies. “At most, if a covered entity refuses to provide the requested data, we will restrict the entity’s use of contract pharmacy arrangements, but these

entities will remain eligible to purchase at 340B prices for shipment to their own facilities," Sanofi leadership said.

On September 1, Eli Lilly and Co. informed 340B contract pharmacies that the company will no longer provide 340B discounts on most of its products to contract pharmacies, reserving program pricing to covered entities alone. Citing President Trump's recent executive order on Access to Affordable Life-saving Medications (EO 13937), the company announced, "Covered entities will not be eligible to purchase Eli Lilly and Company products at the 340B ceiling price for shipment to a contract pharmacy." There is one exception to this policy: Lilly announced that it will continue to provide 340B pricing to contract pharmacies for insulin products so long as covered entities do not mark up the price of the drug.

Recent 340B changes from drug makers have also prompted concerns from Congress. Last week, House Energy and Commerce Committee Chairman Frank Pallone (D-NJ), Health Subcommittee Chairwoman Anna Eshoo (D-CA) and Oversight and Investigations Subcommittee Chair Diana DeGette (D-CO) sent a letter to HHS Secretary Alex Azar expressing concern about pharmaceutical companies]' actions.

"The 340B Program is a critical tool in the fight to lower drug prices, and helps safety net health providers, including Federally Qualified Health Centers and disproportionate share hospitals, among others, to provide frontline care in the midst of the coronavirus disease of 2019 (COVID-19) pandemic," the letter reads. "It is critical that the Administration maintains program integrity to ensure this care is not interrupted."

To read the AHA letter to Sanofi, CLICK HERE.

To read President Trump's recent Executive Order on Access to Affordable Life-saving Medications (EO 13937), CLICK HERE.

To read the E&C Committee members' letter, CLICK HERE.

House Energy & Commerce Committee to Hold Public Hearing on FDA Independence, Pharma Companies Pledge to "Stand with Science" on COVID-19 Vaccines

On August 31, the leadership of the House Energy & Commerce (E&C) Committee announced a planned hearing for September to discuss the FDA's response to the COVID-19 pandemic and its reputation as an independent agency. The announcement comes after the committee held a closed-door briefing with FDA Commissioner Stephan Hahn where members questioned whether the agency faced political pressure from the White House regarding two recent decisions; the emergency use authorization of convalescent plasma and the decision to allow the marketing of laboratory-developed tests without pre-approval.

Following the call, E&C Committee Chairman Frank Pallone (D-NJ) and Health Subcommittee Chairwoman Anna Eshoo (D-CA) issued a statement to the press calling on Commissioner Hahn and other top leaders at the FDA to publicly testify.

“The American people must be able to trust FDA, but recent events, including misleading claims about the efficacy of convalescent plasma, raise serious concerns that the Trump Administration is increasing political pressure on the agency and interfering with its regulatory independence,” the statement reads. “An effective long-term response to COVID-19 is dependent on the availability of treatments and vaccines approved by the agency following its long-held standard of safety and efficacy. Politics should not play any role in these decisions.”

Separately, the chief executives of nine drug companies issued a joint statement today pledging not to seek approval for their coronavirus vaccine candidates unless Phase 3 clinical trials showed they were safe and effective. The pledge was signed by the leaders of AstraZeneca, Johnson & Johnson, Merck & Co., Moderna, Novavax, Pfizer, BioNTech, Sanofi and GlaxoSmithKline and left open the possibility of using partial trial data for an emergency authorization. This announcement comes after David Ricks, chairman-elect of the Pharmaceutical Researchers and Manufacturers Association (PhRMA) and CEO of Eli Lilly stated in an interview with Axios that the industry will “police itself” when it comes to COVID-19 treatments and vaccines.

To view the statement from Reps. Pallone & Eshoo, CLICK HERE.

To view the joint pharmaceutical company statement on COVID-19 vaccines, CLICK HERE.

To read an excerpt from David Ricks’ interview with Axios, CLICK HERE.