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US Oncology Network Commentary: The Promise of the Oncology Care Model

In a new commentary, several members of The Network respond to a recent article in *Health Affairs* that criticized the effectiveness of the Oncology Care Model (OCM). The authors highlight The Network's success with the model and argue that the OCM has been demonstrated to generate cost savings and has the potential to save the U.S. healthcare system even more in the future with successive models. The commentary aims to address three issues related to the *Health Affairs* article:

1. the misperceptions in the discussion of the scope of the problem and the performance of the OCM,
2. the impact of the OCM on the performance and resultant savings achieved by The Network, and
3. the potential place of hospital at home, in not only the OCM, but also in Medicare Advantage programs.

Currently 14 of The Network's practices participate in the OCM, a program sponsored by CMS that provides incentives to improve the quality of cancer care in the Medicare population. If there are savings compared to non-OCM practices, a portion of the savings may be paid to the participating practice.

"The Promise of the Oncology Care Model" was published in *OBR Oncology* on August 2nd and was authored by:

- Russell Hoverman, MD, PhD, Vice President of Quality Programs, Texas Oncology and Medical Director of Managed Care, The US Oncology Network
- Stuart Staggs, Senior Director of Strategic Programs, The US Oncology Network
- Lalan Wilfong, MD, Vice President of Value-Based Care, Texas Oncology
- Marcus Neubauer, MD, Chief Medical Officer, The US Oncology Network
- Lucy Langer, MD, Chair of the National Policy Board Executive Committee, The US Oncology Network and Practice President, Compass Oncology

To read The Network's commentary, CLICK HERE.

To read the *Health Affairs* article, CLICK HERE.

CMS Rescinds Most Favored Nation Model

On August 6, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule to formally rescind the Most Favored Nation (MFN) Model. This action follows the December 28, 2020 nationwide injunction prohibiting CMS from implementing the Model without going through proper notice and comment rulemaking procedures.

In the proposed rule, CMS states, "on July 9, 2021, President Biden signed an Executive Order on Promoting Competition in the American Economy that, in part, directs the Secretary of HHS to take steps to lower the prices of and improve access to prescription drugs and biologicals. HHS is exploring opportunities to promote value-based care for our beneficiaries; to address the high cost of Medicare Part B drugs, manufacturers' pricing, and the resulting growth in Medicare Part B drug spending; and to modernize the Medicare program to improve the quality and cost of care for beneficiaries."

CMS notes its proposal to rescind the MFN Model does not reflect any judgment by the Department of Health and Human Services regarding future policy.

The Network has long opposed the MFN concept through aggressive advocacy efforts and plans to submit robust comments to ensure the MFN Model is fully and formally rescinded.

To read more about The Network's advocacy against the MFN Model, CLICK HERE.

To read the proposed rule to rescind the MFN Model, CLICK HERE.

Senate Passes Bipartisan Infrastructure Bill

Yesterday, the Senate passed a $1 trillion bipartisan infrastructure bill by a vote of 69-30. The bill will fund roads, bridges, broadband, and water infrastructure. The cost of the legislation is offset by repurposing unspent emergency relief funds, increased tax enforcement in certain areas, and revenues from certain user fees and other programs.

Several of the measures used to offset the cost of the bill impact the healthcare sector, including another delay of the Trump Administration's Part D Rebate Rule to 2026 which is expected to generate $59 billion in savings. The original 2022 effective date of the rule, which proposes to eliminate all manufacturer rebates for drugs provided through the Medicare Part D drug program unless the savings are shared with patients at the point of sale, was previously delayed until 2023 by the Biden Administration.

Another provision would require pharmaceutical manufacturers to pay back HHS for wasted drugs from large, single use drug vials which could generate $3 billion in savings over ten years. The change is intended to encourage drug makers to "right size" vials to reduce the amount Medicare reimburses for waste. According to CMS, the top five most-discarded drugs by cost in 2019 were Takeda's Velcade, Roche's Herceptin, Amgen Inc.'s Nplate, Bristol-Myers Squibb Co.'s Abraxane, and Roche's Rituxan.

The legislation would also extend the 2.0% Medicare sequester cuts for an additional year, through

2031, saving the federal government an additional $9 billion.

Speaker Nancy Pelosi has said the House won't take up the bipartisan infrastructure bill until the Senate passes a much larger reconciliation package. As a result, the House is not expected to immediately take up the Senate-passed bipartisan infrastructure bill and it could be several weeks before it does.

To view the text of the infrastructure bill, CLICK HERE.

To view a White House fact sheet on the infrastructure deal, CLICK HERE.

Senate Adopts Budget Resolution, Kickstarting Reconciliation Process

Early this morning, the Senate passed a budget resolution along party lines, paving the way for Senate Democrats to pass a $3.5 trillion spending package without Republican support. As a reminder, the budget resolution provides the framework for the budget reconciliation process, which allows the Senate to pass a variety of reforms with only a simple majority instead of the 60-vote threshold typically required.

Accompanying the budget resolution were instructions to the various Senate committees on which policies to include in the reconciliation bill and how much funding is allocated to each committee to enact those policies. The Senate Finance committee received an instruction requiring at least $1 billion in deficit reduction. The instructions include investment in ACA expansion and closing the Medicaid coverage gap, expanding Medicare to include dental, vision, hearing benefits and lowering the eligibility age, and health equity investments. Offsets include "ensuring that wealthy and large corporations pay their fair share of taxes" and "hundreds of billions in additional savings by lowering the price of prescription drugs."

This follows a letter sent by 12 Senate Democrats to Senate Majority Leader Chuck Schumer (D-NY), Senate Budget Committee Chairman Bernie Sanders and Senate Finance Committee Chairman Ron Wyden (D-OR) urging them to give Medicare the authority to directly negotiate drug prices with pharmaceutical companies in the reconciliation bill. The Senate will continue these negotiations over the August recess.

The budget resolution does not include language to lift the federal debt limit, setting up a showdown for later this year as Senate Democrats will need at least 10 Republican votes to meet the 60-vote requirement under regular order and Senate Minority Leader Mitch McConnell (R-KY) has said Republicans will not vote to raise the debt limit.

Both the House and the Senate must pass the budget resolution for the reconciliation process to advance. Yesterday, House Majority Leader Steny Hoyer (D-MD) announced that the House would return to Washington August 23 to consider the Senate-passed budget resolution. The House had previously been scheduled to return September 20.

To read the text of the budget resolution, CLICK HERE.

To read the accompanying memo, CLICK HERE.

To read the letter calling for drug price negotiation, CLICK HERE.

Senate Advancing Legislation to Increase Generic, Biosimilar Access

On July 29, the Senate Judiciary Committee voted unanimously to advance four bipartisan bills that aim to lower prescription drug costs by increasing access to generic and biosimilar products through antitrust and patent reforms.

One of the reforms, the Prescription Pricing for the People Act of 2021 (S.1388), will require the Federal Trade Commission (FTC) to issue a report about anti-competitive and other potentially abusive practices within the pharmaceutical supply chain that may impact prescription drug costs along with policy recommendations to Congress. Recent consolidations between PBMs and insurance providers have led to only a small number of companies managing most prescription drug benefits.

The committee also advanced:

- the Stop STALLING Act (S. 1425), which would penalize brand drug companies for interfering with the approval of competing generics and biosimilars;
- the Preserve Access to Affordable Generics and Biosimilars Act (S. 1428), which aims to limit the use of pay-for-delay agreements by making the anticompetitive practice increasingly difficult for drug makers to justify in court; and
- the Affordable Prescriptions for Patients Act (S. 1435) which aims to prevent the abuse of patients through product hopping and other practices used to prevent generics and biosimilars from entering the market.

Senators are also urging HHS to support legislation that would allow the personal importation of prescription drugs from Canada. Senators Amy Klobuchar (D-MN), Chuck Grassley (R-IA), Susan Collins (R-ME), and Angus King (I-ME) wrote to HHS Secretary Xavier Becerra recently asking him to back the Safe and Affordable Drugs from Canada Act, a way to combat high drug prices in the United States.

To view the Senate Judiciary Committee hearing, CLICK HERE.

To view the letter on prescription drug importation, CLICK HERE.

FDA Approves First Interchangeable Biologic

On July 28, the Food and Drug Administration made a decision to approve a long-acting insulin called Semglee as the first interchangeable biologic licensed for the U.S. market. As a result of this decision, pharmacists (subject to state law) will be allowed to substitute a biosimilar for its brand-name product without the permission of the original prescriber – a practice that currently only exists for generic drugs.

FDA has been making interchangeability decisions in biologics for quite some time, but only when applied to products from the same sponsor that have been subject to manufacturing changes. The Semglee decision represents the first public regulatory decision anywhere in the world that two biologics from different sponsors can be substituted by someone other than the original prescriber.

In 2010, the Biologics Price Competition and Innovation Act granted the FDA authority to approve biologics made by different sponsors as biosimilars to a previously FDA-approved biologic provided the sponsors can demonstrate that switching between a biosimilar and its reference products has no effect on safety or clinical outcomes. The FDA issued guidance both for interchangeability in general in May 2019 and specifically for insulins in November 2019.

In addition to its decision and approval on the first interchangeable biologic drug, the FDA also released new materials to help health care providers better understand biosimilar and interchangeable biosimilar products.

To view the FDA news release, CLICK HERE.

To view the FDA's Health Care Provider Materials, CLICK HERE.

Broad Coalition Urges Telehealth Extension

On July 26, a broad group of 430 health and technology groups sent a letter to Congress urging an extension of telehealth flexibility for Medicare beneficiaries past the end of the COVID-19 public health emergency. Although a Biden Administration proposed rule would extend temporary Medicare coverage of some telehealth services through December 31, 2023, the groups in the letter say that they don't think the proposal goes far enough and that telehealth should become a permanent fixture in the American healthcare system. The groups also asked Congress to remove the geographic restrictions on patients and providers and to ensure flexibility for which services are eligible for telehealth and how they are delivered, and audio-only services should be permitted for reimbursement by the CMS "when clinically appropriate."

Groups that signed the letter include: the American Medical Association, the American Cancer Society Cancer Action Network, the Association of Community Cancer Centers, the Oncology Nursing Society, and various state oncology societies.

To view the health care coalition telehealth letter, CLICK HERE.