Tuesday, May 4, 2021

Oncology Leaders Examine Practice Efficiency

At a Community Oncology Alliance meeting held last month, oncology leaders including The Network's Chief Medical Officer Marcus Neubauer, MD, discussed the importance of addressing practice efficiencies and improving the patient experience. **Read below.**

President Biden Outlines American Families Plan, Ambitious Legislative Agenda in Address Before Congress

On April 28, before a joint session of Congress, President Biden formally introduced his administration's American Families Plan and reiterated his call for Congress to take bold action to rebuild the American economy following the COVID-19 pandemic. **Read below.**

FDA Reviews Status of Oncology Drugs that Received Accelerated Approval

The U.S. Food and Drug Administration held an advisory committee meeting last week to discuss the status of three immunotherapy drugs that had received accelerated approvals within the past three years but whose manufacturers have not yet been able to demonstrate they could help patients live longer in confirmatory trials. **Read below.**

New CMMI Director Fowler Outlines Path Forward for Alternative Payment Models

In a speech before the National Association of Accountable Care Organizations (NAACOS) on April 20, newly confirmed Centers for Medicare and Medicaid Innovation (CMMI) Director Elizabeth Fowler said the agency was at a "crossroads" as she discussed upcoming plans for Medicare's alterative payment models. **Read below.**

Dozens of Healthcare Organizations Urge CMS to Reverse Trump Administration Policy Allowing Step Therapy in MA Plans

On April 22, approximately 50 organizations representing millions of Medicare beneficiaries with life-threatening, complex, chronic conditions and the physicians who serve them—including The Network — sent a letter to CMS urging the agency to reinstate its policy of prohibiting Medicare Advantage plans from implementing step therapy protocols for Part B drugs. **Read below.**

Bipartisan Members of Congress Urge Biden Administration to Ban Insurer Co-Pay Accumulator Programs

On March 18, a group of more than 50 bipartisan members of the House of Representatives sent a letter to President Biden urging him to lower out-of-pocket drug costs for individuals with private health insurance by prohibiting insurers from using copay accumulator programs to prevent manufacturer cost-sharing assistance from counting towards a beneficiary's deductibles and out-of-pocket maximums. **Read below.**

FULL STORIES

Oncology Leaders Examine Practice Efficiency

At a Community Oncology Alliance (COA) meeting held last month, oncology leaders including The Network's Chief Medical Officer Marcus Neubauer, MD, discussed the importance of addressing practice efficiencies and improving the patient experience during a panel session titled, "Maximizing Practice Efficiencies & Reducing Costs: What Your Practice Can Do Tomorrow."

Experts identified a number of ways to improve practice efficiencies, including innovative patient communication methods and the adoption of new technologies in their practices. Further, oncology leaders discussed the value of decision support tools in navigating scientific literature and prior authorization requirements.

However, oncology leaders acknowledged some of the challenges of efficiently delivering cancer care. "It's difficult to be efficient in an oncologist's world," Dr. Neubauer said during the panel discussion covered by *OBR Oncology*. "The patients are sick. They're dealing with serious diagnosis. They often have other issues such as financial and social concerns."

Dr. Neubauer also discussed the challenges of physician burnout, which more than 30% of The Network's physicians reported experiencing in a recent survey. The Network is currently exploring ways to help oncologists overcome burnout.

To read the *OBR Oncology* article, CLICK HERE.

President Biden Outlines American Families Plan, Ambitious Legislative Agenda in Address Before Congress

On April 28, before a joint session of Congress, President Biden formally introduced his administration's American Families Plan and reiterated his call for Congress to take bold action to rebuild the American economy following the COVID-19 pandemic.

The American Families Plan marks the third major phase of President Biden's bold legislative agenda complementing the recently enacted American Rescue Plan and the American Jobs Plan, an ambitious infrastructure and climate change proposal.

Among the most significant components of the $1.8 trillion American Families Plan:

- $600 billion to permanently extend the one-year tax cuts under the American Rescue Plan. These include expansions of the Child Tax Credit, the Earned Income Tax Credit and the Child and Dependent Care Tax Credit
- $200 billion to make permanent the enhanced Affordable Care Act premium subsidies included in the American Rescue Plan
- $225 billion to implement a national paid family and medical leave program
- $225 billion for childcare for low- and middle-income families
- $200 billion for universal preschool for all three and four-year-old children
- $109 billion for two years of free community college, plus $85 billion for Pell Grants, $62 billion for student retention programs, and $46 billion for Historically Black Colleges and Universities, Tribal Colleges and Universities, and Minority Serving Institutions

The administration says the new spending will be offset by rolling back portions of the 2017 Tax Cuts and Jobs Act, increasing the top marginal tax rate to pre-2017 levels, raising the capital gains tax and

increasing tax enforcement by allocating billions of additional dollars to the IRS.

President Biden also called for a renewed bipartisan effort to “end cancer as we know it” and reiterated his administration’s proposal to establish an Advanced Research Projects Agency for Health (ARPA-H) within the National Institutes of Health that would be tasked with driving “transformational innovation” in the areas of cancer care as well as other chronic diseases including Alzheimer’s and diabetes.

Notably absent from the American Families Plan is a proposal to address the high cost of prescription drug prices, although President Biden did call on Congress to pass legislation to allow Medicare to negotiate prescription drug prices in his speech - a policy popular among many congressional Democrats and included in H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act.

Democratic leaders, including House Energy & Commerce (E&C) Committee Chair Frank Pallone (D-NJ) and Senate Finance Committee Chair Ron Wyden (D-OR) have said that they remain committed to keeping drug pricing reform on the legislative agenda and will seek to include it in forthcoming infrastructure legislation. On May 4, the E&C Health Subcommittee held a hearing on H.R. 3 and several other drug pricing bills including H.R. 19, a Republican-led effort to reduce drug prices without allowing Medicare to directly negotiate.

In the days leading up to the release of the American Families Plan, President Biden faced calls from congressional Democrats on a variety of drug pricing and Medicare measures. A group of more than 100 Democratic lawmakers signed a letter led by House Progressive Caucus Co-Chair Rep. Pramila Jayapal (D-WA) and Senator Bernie Sanders (I-VT) urging Biden to include Medicare expansion and drug price negotiation in the American Families Plan. Meanwhile, a group of moderate-leaning Democrats known as the New Democrat Coalition issued their own set of priorities that includes less ambitious proposals such as making permanent the enhanced ACA subsidies from the American Rescue Plan, creating a national reinsurance program to stabilize the individual marketplace and encouraging states to auto-enroll uninsured people who qualify for insurance plans with $0 premiums. The New Democrat Coalition also backed a proposal to streamline prior authorization similar to the Improving Seniors’ Timely Access to Care Act.

To view the text of President Biden’s address, CLICK HERE.

To view a White House fact sheet on the American Families Plan, CLICK HERE.

To view the House Energy & Commerce Committee Hearing, CLICK HERE.

To view the Jayapal-Sanders letter urging Medicare expansion, CLICK HERE.

To view the New Democrat Coalition priorities, CLICK HERE.

FDA Reviews Status of Oncology Drugs that Received Accelerated Approval

The U.S. Food and Drug Administration held an advisory committee meeting last week to discuss the status of three immunotherapy drugs that had received accelerated approvals within the past three years but whose manufacturers have not yet been able to demonstrate if they could help patients live longer in confirmatory trials. During the three-day meeting, the FDA asked Merck, Roche and Bristol-Myers Squibb – the manufacturers of the drugs under scrutiny – to provide updated data that demonstrates how the drugs improve or extend life.

The committee examined Tecentriq's approval for breast and bladder cancer, Keytruda's approval for bladder, stomach, and liver cancer, and Opdivo's approval for liver cancer, and recommended the FDA maintain four of the six approvals. The advisory committee, made up of oncologists and patient representatives, repeatedly expressed reservations about withdrawing treatments for patients with limited options.

This April's advisory committee meeting is only the fourth such panel the FDA has convened in its history. The last meeting in which the FDA considered removing approvals for expensive drugs on the market that had received expedited approval but failed to live up to their promise was held 10 years ago. Since the FDA was granted the power to accelerate drug approvals based on preliminary study data, it has used its authority to revoke an accelerated cancer approval only once. Out of 155 expedited approvals for cancer drugs, only 10 have been voluntarily withdrawn by the manufacturer—four of which came since the end of 2020.

To read the FDA's meeting and event materials, CLICK HERE.

To read an analysis of the meeting, CLICK HERE and HERE.

New CMMI Director Fowler Outlines Path Forward for Alternative Payment Models

In a speech before the National Association of Accountable Care Organizations (NAACOS) April 20, newly confirmed Centers for Medicare and Medicaid Innovation (CMMI) Director Elizabeth Fowler said the agency was at a "crossroads" as she discussed upcoming plans for Medicare's alternative payment models. Dr. Fowler urged patience on the part of providers who have been frustrated by the recent decision to put several models on hold for additional review including the Primary Care First, Geographic Direct Contracting models, Kidney Care Choices and the Chart ACO track.

"I understand that, collectively, these announcements may have led to questions about where the center is headed next. And I want to be clear that our commitment to value-based care has never been stronger," Dr. Fowler told the group. "We want the CMS Innovation Center to work to lower costs, improve quality of patient care, and better align payment systems to promote patient-centered practices. But we also need to be honest about the nature of innovation — that not everything is going to be a home run. Some things will work, others won't. And we need to be agile. True innovation means failing until we get things right. And it's just as important to learn from what doesn't work and be transparent about those findings so we can continue to refine, evolve and grow."

Noting that COVID-19 has exposed and exacerbated vast racial disparities within the American healthcare system, Fowler pledged that CMMI will approach these and future models through a health equity lens. The agency will also look to expand its reach into Medicaid and engage other payers in the process as it works to align its agenda with the Biden Administration's health policy priorities.

Further, Fowler noted in a follow-up Q&A that CMMI may be looking at having fewer models in the future and that other metrics of success beyond cost savings may be receiving greater weight.

To read more about Director Fowler's remarks at the NAACOS conference, CLICK HERE.

Dozens of Healthcare Organizations Urge CMS to Reverse Trump Administration Policy Allowing Step Therapy in MA Plans

On April 22, approximately 50 organizations representing millions of Medicare beneficiaries with life-threatening, complex, chronic conditions and the physicians who serve them—including The Network—sent a letter to CMS urging the agency to reinstate its policy of prohibiting Medicare Advantage plans from implementing step therapy protocols for Part B drugs. The original prohibition was rescinded by the Trump Administration in 2018 and took effect the following year.

“We hope that the new administration will consider immediately reversing the harmful decision to allow step therapy,” the letter states. “At the same time, we encourage CMS to continue its work with patients, physicians, and other key stakeholders to develop other solutions that will ensure Medicare beneficiaries continue to have timely access to the clinical treatments they need while lowering the cost of medications for patients and the Medicare program. This is an urgent first step in ensuring a broad, evidence based pharmaceutical benefit for the beneficiaries.”

Step therapy, also known as “fail first,” is a practice used by health insurance companies to force patients to first try and “fail” a drug preferred by the insurer before a patient can be approved the treatment their provider originally prescribed. Billed as a cost-control measure, the practice frequently results in disruptions in the continuity of care and can lead to adverse outcomes for some patients.

To read the letter, CLICK HERE.

Bipartisan Members of Congress Urge Biden Administration to Ban Insurer Copay Accumulator Programs

On March 18, a group of more than 50 bipartisan members of the House of Representatives sent a letter to President Biden urging him to lower out-of-pocket drug costs for individuals with private health insurance by prohibiting insurers from using copay accumulator programs to prevent manufacturer cost-sharing assistance from counting towards a beneficiary’s deductibles and out-of-pocket maximums. The letter was led by Representatives Donald McEachin (D-VA) and Rodney Davis (R-IL).

The letter highlights a provision in the 2021 Notice of Benefit and Payment Parameters (NBPP) rule that permits insurers and PBMs to implement these programs.

“During a global pandemic, we should be doing everything we can to increase affordability of prescription drugs, not decrease it, and reversing the 2021 NBPP copay accumulator policy will help people save more money at the pharmacy counter”, the lawmakers wrote. “We urge you to consider reversing this policy to enable Americans to afford the lifesaving medication they rely on.”

The lawmakers argue that the NBPP is out of step with both congressional intent and Department of Health and Human Services (HHS) policy. “We believe that the 2021 NBPP does not align with the U.S. Department of Health and Human Services’ (HHS) own regulation defining cost-sharing – which includes payments made by or on behalf of an insured – nor does it align with Congressional intent in defining cost-sharing and establishing the annual limit on cost-sharing,” they write.

On April 30, HHS released a second 2022 NBPP rule to complement the first rule issued by the Trump Administration on January 14. Stakeholders critical of the use of copay accumulator programs were hopeful the Biden Administration would roll back the Trump-era policy in the second final rule.

The Biden HHS appears content to let the copay accumulator policy stand, though it did lower the beneficiary out-of-pocket maximum by $400 relative to the proposed rule, among other changes.

To read the letter, CLICK HERE.

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

To read the text of the second NBPP final rule, CLICK HERE.