
Health Policy Update – December 8, 2020

The Network Featured in American Journal of Managed Care Article, Podcast

In late November, the *American Journal of Managed Care (AJMC)* featured The US Oncology Network in a profile of the Oncology Care Model. Noting that participation in the OCM has been challenging for many stakeholders, AJMC highlighted the broad success The Network has had in the model due to both its commitment to practice transformation and resources. The Network recently hit a milestone of 100,000 patients enrolled in the model since its inception.

Marcus Neubauer, MD, chief medical officer of The Network; and Stuart Staggs, senior director of Strategic Programs at McKesson, were both quoted discussing the steps that successful oncology practices have taken to improve patient outcomes and achieve system-wide cost savings while participating in the OCM.

“Getting your practice to understand the model and participate in it is absolutely a practice-wide undertaking. This is not something that an administrator can do, or one or two physicians can do on their own, it has to be a practice-wide effort,” Dr. Neubauer told AJMC. “So there were major challenges with this, but also a lot of opportunity and a lot of excitement in our practices even way back in 2016, to be a part of what they sought to be this transition to value-based care.”

“One of the big things that we're seeing is with practices that have really bought in, they've not only done these activities and enhanced services for Medicare patients; they've expanded those same good habits and broader services to even non-Medicare patients,” Staggs said.

The AJMC also featured The Network's leadership in a podcast episode published by the journal's Center for Biosimilars. Dr. Neubauer, along with Kathryn Tong, vice president of Payer, Pharmacy, Analytics & Transformation at McKesson and Tommy Pourmahram, vice president of Multi-Source & Analytics for McKesson sat down with AJMC editors to discuss the factors currently impacting US biosimilar adoption rates, what reforms are needed to improve it, and what stakeholders can do to help.

To read the AJMC article on the Network's experience with the OCM, [CLICK HERE](#).

To listen to the Center for Biosimilars podcast, [CLICK HERE](#).

President-elect Joe Biden Announces Nomination for HHS Secretary and Other Key Members of Health Team

On December 7, President-elect Joe Biden formally unveiled his picks for the nation's top healthcare policymakers. Biden plans to nominate California Attorney General Xavier Becerra to be the next Secretary of Health and Human Services.

As Attorney General, Becerra has distinguished himself as a strong advocate for expanding Americans' access to healthcare and recently defended the Affordable Care Act before the Supreme Court in the case *Texas v. U.S.* Before his election to statewide office, Becerra was a member of Congress serving southern California for nearly 25 years where he sat on the House Ways and Means subcommittee overseeing health issues and was a vocal proponent for passing the ACA. If confirmed by the Senate, Becerra would be the first Latino to lead HHS.

In addition to Becerra, President-elect Biden also announced Dr. Rochelle Walensky as his pick for Director of the Centers for Disease Control and Prevention. Dr. Walensky is the chief of infectious diseases at Massachusetts General Hospital and a professor of medicine at Harvard Medical School with a specialty in HIV/AIDS.

Biden also made several other announcements regarding his healthcare policy team:

- Former U.S. Surgeon General Dr. Vivek Murthy will return to that position with an expanded portfolio that includes COVID-19 response. Dr. Murthy served as Surgeon General in the Obama Administration from 2014 - 2017.
- Dr. Anthony Fauci, the current Director of the National Institute of Allergy and Infectious Diseases will continue in his position and will also serve as Chief Medical Advisor to the President on COVID-19.
- Dr. Marcella Nunez-Smith, an associate Professor of Medicine, Public Health, and Management at the Yale School of Medicine and the founding director of Yale's Equity Research and Innovation Center was selected to serve as the new Administration's COVID-19 Equity Task Force Chair.
- Jeff Zients – a longtime advisor to President-elect Biden – will serve as Coordinator of the COVID-19 Response and Counselor to the President.
- Natalie Quillian will be Deputy Coordinator of COVID-19 Response. Quillian served in a number of positions in the Obama Administration including coordinating the interagency response to the opioid epidemic and was most recently Deputy Campaign Manager for Biden's Presidential Campaign.

To view Biden's Transition Team's announcement of these nominations, [CLICK HERE](#).

CMS Finalizes 2021 Physician Fee Schedule, Quality Payment Program and Hospital Outpatient Department & Ambulatory Surgery Center Payment Rules

Last week, the Centers for Medicare & Medicaid Services unveiled final Medicare payment rules to be implemented at the start of 2021.

Included in the Physician Fee Schedule (PFS)/Quality Payment Program (QPP) final rule is a \$3.68 decrease in the conversion factor – to \$32.41 – in order to reflect the budget neutrality adjustment to account for payment increases for E/M services. While The Network urged CMS to waive budget neutrality, the agency claims it lacks the necessary authority. Therefore, the focus will now move to Congress to address the adjustment, which will negatively impact providers. The E/M coding change, which was finalized last year, is largely aligned with the recommendation of the American Medical Association.

The PFS rule also added more than 60 services to the Medicare telehealth list on either a permanent or temporary basis and established payment for an extended audio-only or virtual check-in service on an interim final basis. Further, the rule adopted a policy for the duration of the public health emergency that permits direct supervision via virtual presence of the supervising physician or practitioner using interactive audio/video real-time communication.

The QPP rule delayed the implementation of the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) until 2022 and introduced a new Alternative Payment Model (APM) Performance Pathway (APP).

In the Hospital Outpatient Prospective Payment System (OPPS) rule, which was also finalized last week, CMS declined to move forward with more aggressive cuts to 340B drug reimbursement. It instead finalized an alternative proposal to continue paying hospitals for those drugs at the Average Sales Price minus 22.5%, but stated that it will continue to consider and evaluate the appropriateness of using 340B hospital survey data to set future payment rates for 340B drugs.

Further, the OPPS rule codified CMS's previously announced delay of the Radiation Oncology Model to July 2021. CMS originally announced this delay last month after stakeholders raised concerns about the short time frame in which the model was to be implemented.

To view CMS' announcement of the 2021 PFS/QPP final rule, [CLICK HERE](#).

To view the text of the 2021 PFS/QPP final rule, [CLICK HERE](#).

To view CMS' announcement of the 2021 OPPS/ASC final rule, [CLICK HERE](#).

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Contact Your Member of Congress to Stop Physician Payment Cuts

In March, Congress temporarily suspended the 2% Medicare sequester cut as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, providing much needed relief to practices experiencing hardship due to the COVID-19 pandemic. This suspension is set to expire on December 31, 2020, and The Network is urging lawmakers to extend the Medicare sequester relief through 2021 in the upcoming year-end spending bill.

In a related push, ASTRO is urging its membership to ask their lawmakers to support the Holding Providers Harmless from Medicare Cuts During COVID-19 Act of 2020 (H.R. 8702). This bipartisan legislation, which was introduced by Representatives Ami Bera, MD (D-CA) and Larry Bucshon, MD (R-IN), would effectively freeze Medicare payments at 2020 rates for negatively impacted services, while implementing scheduled reimbursement increases for positively impacted services, including E/M services. The need for this legislation has been met with renewed urgency after CMS finalized the 2021 Physician Fee Schedule rule without waiving the budget neutrality adjustment.

ACT NOW: Contact Congress to extend Medicare sequester relief by [CLICK HERE](#).

ACT NOW: Contact Congress to Support H.R. 8702 by [CLICK HERE](#).

Lawsuits Filed to Stop Trump Administration Most Favored Nation and Drug Importation Rules

Organizations representing specialty providers, the pharmaceutical industry, and patient advocates have filed lawsuits in federal court challenging the Trump Administration's recent rules concerning prescription drug prices.

On December 4, the Association of Community Cancer Centers (ACCC), the Global Colon Cancer Association, the National Infusion Center Association (NICA), and the Pharmaceutical Research and Manufacturers of America (PhRMA) sued the Trump Administration over the recently announced Most Favored Nation (MFN) interim final rule. The groups allege that the rule exceeds the Administration's authority under the Social Security Act and violates that Administrative Procedure Act by issuing a final rule without allowing meaningful public comment. Further, the groups argue that the rule will "irreparably harm patients, care providers, physicians, pharmaceutical manufacturers, and the broader public interest in innovation and discovery in the pharmaceutical field." The plaintiffs are seeking a preliminary and permanent injunction against the enforcement of the MFN Rule, including a temporary restraining order, a declaration that the MFN Rule is unconstitutional and invalid, and other appropriate relief. Biotechnology Innovation Organization (BIO), Biocom California, and the California Life Sciences Association (CLSA) also filed suit challenging the MFN rule on Friday.

Separately, on November 23, PhRMA filed a lawsuit over the Trump Administration's rule allowing states to import prescription drugs from Canada with FDA approval. PhRMA, which was joined in its lawsuit by the Partnership for Safe Medicines and the Council for Affordable Health Coverage, argues that the rule would not save consumers money, poses risks to public health and compromises drug makers' trade secrets.

Though the Trump Administration insists that this rule would be a "game changer for American seniors," it has been met with resistance by drug manufacturers, pharmacists and the Canadian government. On November 27, the Canadian government announced that it would block the distribution of particular drugs outside of Canada if the sales would cause or intensify a drug shortage. Specific drugs were not named by the government.

To read the ACCC complaint against the MFN rule, [CLICK HERE](#).

To read the BIO complaint against the MFN rule, [CLICK HERE](#).

To read the news release from Health Canada, [CLICK HERE](#).

Congress Continues to Debate End-of-Year Spending Package, COVID-19 Relief

As the clock winds down for the 116th Congress, lawmakers from both parties have worked to advance an omnibus spending package before funding expires for nearly every federal agency on December 11. Meanwhile, negotiations continue on the next package of relief for individuals, businesses, and state and local governments impacted by the COVID-19 pandemic.

On COVID-19 relief, House Speaker Nancy Pelosi and Senate Minority Leader Chuck Schumer officially threw their support behind a \$908 billion bipartisan framework introduced last week by a bicameral working group consisting of Senators Bill Cassidy (R-LA.), Susan Collins (R-ME), Angus King (I-ME), Joe Manchin III (D-WV), Mitt Romney (R-UT) and Mark R. Warner (D-VA) and Representatives Josh Gottheimer (D-NJ), Tom Reed (R-NY), Anthony Gonzalez (R-OH), Dusty Johnson (R-SD), Dean Phillips (D-MN), Abigail Spanberger (D-VA), and Fred Upton (R-MI).

While Democratic leadership had originally embraced a much more expansive relief package, Pelosi and Schumer have settled on the bipartisan legislation that they believe has the best chance of passage. Meanwhile, Senate Majority Leader McConnell has insisted on a smaller and more narrowly targeted package that he claims already has the White House' approval. Due to uncertainty over the future of the next COVID-19 relief package, many healthcare stakeholders are advocating for policies related to pandemic relief to be included in the end-of-year spending package.

State governments and healthcare associations have called on Congress to include a provision in the omnibus that would extend the deadline for spending funds allocated by the CARES Act. Without an extension, state and local governments will be forced to return any unspent federal funds, a requirement that they say causes an incentive to focus on short-term spending instead of planning to use the funds for more long-term emergency relief projects.

After meeting virtually with state governors, President-elect Joe Biden spoke out in favor of providing relief and flexibility to state and local governments. "The lost revenue from COVID and the cost of COVID recovery is devastating to state and local budgets as governors - as all of them indicated," Biden said. "We've got to come together. The federal government has got to deliver this relief sooner rather than later and with flexibilities for the states to meet their needs."

To view the bipartisan COVID-19 relief framework, [CLICK HERE](#).

To view Leader McConnell's legislation, [CLICK HERE](#).

White House Finalizes Overhaul of Stark Anti-Kickback Statutes

In mid-November the Department of Health and Human Services finalized long-awaited overhauls to the Stark and anti-kickback laws with the aim of making it easier for providers to enter value-based care arrangements. The two rules reevaluate existing safe harbor provisions under the anti-kickback statute and create new exemptions to add greater flexibility for care coordination while still providing a safeguard against fraud. The final rules lower the level of downside risk necessary to qualify for the new safe harbors, in response to concerns from providers, and include a provision that would allow hospitals to share cybersecurity tools with providers that have fewer resources.

The provider community's response so far has ranged from supportive to lukewarm. In particular, the American Hospital Association, Federation of American Hospitals and America's Essential Hospitals were encouraged by HHS' efforts to reform physician self-referral and anti-kickback rules but others say some areas still need a lot of work.

Some groups argue healthcare organizations need more clarity than the new rules allow because they need to make administrative, financial, operational and clinical changes for different arrangements and exceptions. Reviewing the new changes will take significant time, and still might not entice some providers to engage in value-based care arrangements. Still, others were leery of tying Stark law exemptions to price transparency requirements which has been a key part of the Administration's strategy to address healthcare costs by giving patients more information about their out-of-pocket costs for referred items and services.

Both rules will go into effect Jan. 19, one day before President-elect Joe Biden is sworn into office. While the new Administration could revisit the rules in the future, recent changes have carried bipartisan and industry support and are not expected to change any time soon.

To view HHS' announcement of the Stark and anti-kickback reforms, [CLICK HERE](#).

To view an HHS Q&A about the reforms, [CLICK HERE](#).