Health Policy Update – March 11, 2020

The Network Urges CMS to Drop Copay Accumulator Provision from 2021 NBPP Proposed Rule

In comments to the Centers for Medicare & Medicaid Services (CMS) 2021 Notice of Benefit and Payment Parameters (NBPP) Proposed Rule, The Network urged the agency to drop its plan to permit insurance plans to utilize "copay accumulators" to exclude drug manufacturer discount coupons from counting towards a beneficiary's deductible or out-of-pocket maximum costs. Under the proposal, all commercial health insurance plans would be able to apply co-pay accumulators towards any drug, an expansion of current policy which limited their application to manufacturer assistance for branded drugs where a "medically appropriate" generic equivalent is available and was not enforced by CMS.

The Network expressed its concerns that such a policy would result in more plans utilizing co-pay accumulators and disproportionally target cancer patients who already struggle to afford the life-saving therapies they need. The Network noted that recent advances in cancer treatment have led to improved, more personalized, and targeted treatment regimens and a lower-priced alternative exist. As a result, this policy is more likely lead to additional cost burden for patients, threatening treatment adherence and potentially resulting in negative outcomes.

To read The Network's comments to CMS, **CLICK HERE**.

Dr. Thaker Discusses How Practices Can Use Big Data Analytics to Prepare for Proposed Radiation Oncology Model in Journal of Oncology Practice

On March 10, the *Journal of Oncology Practice* published a paper from Dr. Nikhil Thaker of Arizona Oncology and seven other representatives from The US Oncology Network and McKesson Corporation exploring how automated big data analytics can be used to calculate a radiation oncology practice's historical disease site-specific episode costs and help improve the proposed Radiation Oncology Alternative Payment Model (RO-APM).

Authored by Dr. Nikhil Thaker, and Joshua Holloway, Chas Hodapp, Michael Mellen, Dr. David Fryefield, Rehman Meghani, Kathryn Tong, and Dr. Christopher Rose of The US Oncology Network and McKesson Corporation, the paper explains how a custom-built software tool was used to analyze claims data from Network radiation oncology practices to determine the impact of certain aspects of the proposed RO-APM as well as potential changes to the model. The authors note that as payment models continue to shift from volume to value, practices will need an automated analytics tool to measure historical costs and prepare for operational and financial transformation.

To view the paper, **CLICK HERE**.

Congress Passes Supplemental Funding Bill to Address COVID19 as Federal Agencies Release Updates

In response to growing concerns about the impact of COVID-19, Congress overwhelmingly passed, and the President signed, an $8.3 billion supplemental funding bill to support federal efforts to prevent, prepare for and respond to the disease. The package includes:

- $3.1 billion to the Public Health and Social Services Emergency Fund and HHS Office of the Assistant Secretary for Preparedness and Response to procure medical supplies and supplement the Strategic National Stockpile;
- $2.2 billion to the Centers for Disease Control and Prevention;
- $1.3 billion to State Department assist with the evacuation of diplomats and U.S. citizens abroad and boost global health programs;
- $836 million to the National Institutes of Health;
- $500 million to support Medicare telehealth programs;
- $61 million to the FDA for pre- and post-market work the development and approval of new therapies and vaccines and efforts to monitor and mitigate medical product shortages; and
- $20 million to the Small Business Administration for loans to businesses affected by the spread of COVID-19.

In addition, the legislation allows HHS to temporarily waive certain Medicare restrictions and requirements regarding telehealth services during the coronavirus public health emergency. The bill was signed into law on March 6.

In a commentary published in the New England Journal of Medicine, CDC Director Robert Redfield, MD, National Institute of Allergy and Infectious Disease (NIAID) Director Anthony Fauci, MD and NIAID Deputy Director H. Clifford Lane, MD outline the federal government's response to the COVID-19 epidemic and discus the latest research on the disease.

Further, the U.S. Food and Drug Administration (FDA) published on its website a list of its ongoing efforts to respond to the epidemic, including a notice that it is currently monitoring the U.S. pharmaceutical supply chain for shortages.

To read the text of the COVID-19 supplemental funding bill, **CLICK HERE**.

To receive the latest updates from the FDA regarding COVID-19, **CLICK HERE**.

To read Drs. Redfield, Fauci, and Lane's commentary in NJEM, **CLICK HERE**.

CMS and ONC Release Final Interoperability Rules, HHS Releases Strategy to Reduce EHR Administrative Burdens

On March 9, the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) released a pair of long-awaited rules governing healthcare interoperability and data blocking.

The final rules largely mirror the proposed rules and are designed to make it easier for providers, insurers, and patients to access and share health data. The ONC final rule standardizes application programming interfaces (APIs), which support a patient's access and control of their health information, and establishes new requirements to prevent "information blocking" practices (e.g., anti-competitive behaviors) by healthcare providers, developers of certified health IT, health information exchanges, and health information networks. The CMS Interoperability and Patient Access final rule requires health plans in Medicare Advantage, Medicaid, Children's Health Insurance Program (CHIP), and the federal Exchanges to share claims data electronically with patients beginning on or after January 1, 2021. The CMS rule also establishes a new Condition of Participation for all Medicare and Medicaid participating hospitals, requiring them to send electronic notifications to other providers when a patient is admitted, discharged or transferred.

"Delivering interoperability actually gives patients the ability to manage their healthcare the same way they manage their finances, travel and every other component of their lives. This requires using modern computing standards and APIs that give patients access to their health information and give them the ability to use the tools they want to shop for and

coordinate their own care on their smartphones," said Don Rucker, M.D., national coordinator for health information technology.

Separately, the ONC unveiled a new strategy to reduce EHR administrative burdens. The final strategy, which was mandated by the 21st Century Cures Act, highlighted four primary areas that contribute to administrative burdens: clinical documentation; health information technology usability; public health reporting requirements, and federal health IT and EHR reporting requirements. It also identified steps the federal government can take to address these challenges such as making changes to improving the clinician user experience and reducing redundant reporting requirements.

To read the HHS Press Release on the Interoperability Final Rules, **CLICK HERE**.

To read the ONC Final Rule, **CLICK HERE**.

To read the CMS Interoperability and Patient Access Final Rule, **CLICK HERE**.

To view the ONC's EHR administrative burden strategy, **CLICK HERE**.

New Research Shows Pharmacy DIR Fees Hit a Record $9 Billion in 2019

A new report from Drug Channels, a blog that covers the pharmaceutical distribution system, found that pharmacies paid a record $9.1 billion in fees to Part D plans last year and that pharmacy fees accounted for 18 percent of all Medicare Part D rebates. This is a significant increase from 2013, where pharmacies paid $229 million in Part D price concessions.

These new findings come amid recent action on the part of CMS to require plans to disclose performance measures in an effort to ensure pharmacy benefit managers (PBM) aren't abusing Part D price concessions. In recent years, pharmacies have argued that Direct and Indirect Renumeration (DIR) fees, most of which are collected from pharmacies after the medication is dispensed, have not only become a serious burden for pharmacies but are being used to boost PBM revenue. DIR fees, as defined in the Drug Channels report, consist of manufacturer price concessions as well as performance-based fees levied by PBMs.

To read the Drug Channels report, **CLICK HERE**.

Study Finds Medicaid Expansion Fails to Spur More Hospital Charity Care Spending

A new study in the Journal of the American Medical Association examined the connection between the Affordable Care Act's (ACA) expansion of the Medicaid program and hospital spending on charitable activities.

According to the research, in the years following the Medicaid expansion under the ACA, tax-exempt hospitals in expansion states reported significant decreases in uncompensated care. In this study, these decreases were not accompanied by increases in other types of community benefit spending, such as community health investment or community-building activities, but instead by increases in reported unreimbursed Medicaid expenses.

To read the JAMA study, **CLICK HERE**.

Supreme Court Will Hear Third Challenge to Affordable Care Act

On March 2, the Supreme Court agreed to hear a constitutional challenge to the Affordable Care Act (ACA) brought by the Attorneys General of Texas and 17 other states. The court is expected to rule on whether the ACA's individual mandate is unconstitutional and, if so, whether the rest of the law should be struck down as a result.

Last year, a three-judge appellate panel ruled in the Texas case that the ACA's individual mandate was unconstitutional but deferred to a lower court as to whether the rest of the law should be dismantled. That decision was appealed to the Supreme Court late last year.

This case will be the third time the Supreme Court hears a challenge to dismantle the ACA. In both previous challenges the Court has ruled that both the ACA, and the individual mandate, were constitutional.

The court is expected to hear the case during its next term which starts in October, but a ruling may not occur until after the election.