issues

ACCC Joins Lawsuit Against MFN Final Rule

BY CHRISTIAN G. DOWNS, JD, MHA

n Friday, Nov. 20, 2020, the Centers for Medicare & Medicaid Services (CMS) released the Most Favored Nation (MFN) Model Interim Final Rule with Comment Period. The model is mandatory for all Medicare physicians, non-physician practitioners, supplier groups (such as group practices), hospital outpatient departments (including 340B covered entities), ambulatory surgical centers, and other providers and suppliers that receive separate Medicare Part B fee-for-service payment for the model's included drugs, with certain exceptions.

The Model was set to begin on Jan. 1, 2021, and would operate for seven years. On December 23, a federal court issued a temporary restraining order blocking CMS from implementing the MFN Interim Final Rule on January 1.

If implemented, the first year of the demonstration includes 50 Part B drugs that encompass a high percentage of Medicare Part B drug spending. Instead of paying for these drugs based on the manufacturer's average sales price, Medicare will pay the MFN price, which will be based on the lowest per capita gross domestic product-adjusted price of any country in the market basket.

This model, if implemented, will have a devastating impact on cancer programs and practices already experiencing great financial hardship due to COVID-19 and the public health emergency. Additionally, cancer programs and practices in rural and underserved areas that have a high proportion of Medicare patients may be forced to close, consolidate, and/or reduce critical services with the decrease in reimbursement and the increase in administrative burden if the model goes into effect. Most important, this model will reduce or eliminate Medicare beneficiaries' access to quality care. In fact, the rule acknowledges that a portion of the savings CMS expects to realize under the model is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization.

To prevent implementation of the model, ACCC joined with the Global Colon Cancer Association, the National Infusion Center Association, and the Pharmaceutical Research and Manufacturers of America to file a lawsuit against the U.S. Department of Health and Human Services, seeking an immediate injunction to prevent the implementation of the MFN model. Other stakeholder organizations, including the Community Oncology Alliance, soon filed additional lawsuits against the MFN model.

ACCC's request for an injunction was based on CMS's violation of the Administrative Procedure Act, which requires an agency to issue a proposed rule and allow for notice and comment from interested stakeholders before a final regulation is published. CMS violated the Administrative Procedure Act by implementing the MFN model through an interim final rule, with no Notice of Proposed Rulemaking and no opportunity for public comment. Further, a waiver of notice and comment must be supported by a showing of good cause, which we believe CMS has failed to demonstrate.

In other ACCC news, please join me in welcoming Kristin Ferguson, DPN, RN, OCN, as senior director of care delivery and policy. Dr. Ferguson brings more than a decade of experience in oncology care reflecting not only the versatile skill set that oncology nurses command but also the expanding roles that nurses play in cancer care delivery. In addition to clinical experience in both the inpatient and outpatient settings, Dr. Ferguson has served as a clinical research coordinator, a nursing coordinator, and a nurse administrator at a National Cancer Institute-designated cancer center. She serves on the Oncology Nursing Society board and has participated in Oncology Nursing Society advocacy initiatives, interned with the Community Oncology Alliance, and volunteered extensively in her community.

Dr. Ferguson will take over this column with the next Oncology Issues. In March, Dr. Ferguson, ACCC members, and stakeholders from across oncology will come together virtually at the ACCC 47th Annual Meeting & Cancer Center Business Summit, March 1-5. Real-world case studies will demonstrate how to lead through change, accelerate digital health capabilities, transform business operations and care processes, and enhance the patient and provider experience. In a climate of ongoing uncertainty, complexity, and relentless change, the ACCC 47th Annual Meeting & Cancer Center Business Summit offers an opportunity to experience equilibrium while gaining perspective on priorities and how best to prepare for challenges to cancer care delivery on the horizon. Learn more at accc-cancer. org/AMCCBS. 🖸

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