Florida Society of Clinical Oncology

The Voice of Oncology in Florida

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January 6, 2021

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Most Favored Nation (MFN) Model, Interim Final Rule with Comment Period (IFC); 85 FR 76180; CMS-5528-IFC

Submitted electronically at www.regulations.gov

Dear Administrator Verma,

As President of the Florida Society of Clinical Oncology (FLASCO), I am writing you on behalf of the FLASCO membership which consists of more than 3,700 oncology healthcare providers in Florida. We are submitting comments on behalf of FLASCO strongly opposing the interim final rule published in the Federal Register on November 27, 2020 and effective on the date of publication.

FLASCO is the largest chapter of the American Society of Clinical Oncology (ASCO) with more than 3,700 members, we represent stakeholders that are very involve in the delivery of cancer care in this country and the treatment of cancer patients.

The Most Favored Nation (MFN) Model sets reimbursement for 50 Medicare Part B drugs at the lowest price available in a comparator set of approximately 22 countries and adds a flat, fixed add-on payment that replaces the current ASP+6 (Average Sales Price + 6%). The model completely fails to address the high price of drugs, or to lower drug prices; nowhere in the rule is price-setting by manufacturers expressly addressed as a requirement of the MFN model. Instead, it relies heavily on lower utilization to achieve projected savings and places the onus for finding any savings squarely on health care providers.

The model would artificially lower reimbursement for drugs to physicians, potentially well below U.S. market price, while physicians will have no option but to continue to pay U.S. market rates for acquisition. The result would be physicians and practices either absorbing significant financial losses or being unable to offer these treatments to their patients.

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The rule plainly states that patients who cannot get care from regular providers will have to seek treatment elsewhere and that some patients will simply go untreated. Nearly 1 in 5 patients will be unable to secure care anywhere and will likely forgo essential, life-prolonging treatment (i.e. a 19% decrease in utilization). The model as envisioned "saves" money in part by reducing Medicare beneficiary access to appropriate care.

CMS also claims that Medicare beneficiaries will see large savings due to reduced out-of-pocket costs in the MFN Model. These savings would come from a declining 20% beneficiary co-pay on the drug itself with declining reimbursement for these drugs, and because beneficiaries would not have to pay a co-pay on the drug "add-on" payment. However, one independent analysis found that the vast majority of beneficiaries in Medicare FFS would not see a reduction in their out-of-pocket costs from the MFN model because more than 94% of FFS Part B beneficiaries using MFN drugs have supplemental coverage that covers some or all of their cost-sharing for Part B drugs. The analysis estimated that less than 1% of beneficiaries in Medicare would see reduced out-of-pocket costs based on the 50 drugs listed in the IFC. This rule and the MFN Model are of special concern to the oncology community, as the financial burden of the model is borne primarily by cancer care specialties. Of the 50 MFN drugs, hematology/oncology is listed as the top billing specialty for 29 drugs and is included in the top three specialties for a total of 38 drugs. A decrease in utilization of 19% of these life-saving drugs translates into years of life lost and untold suffering for patients and their loved ones. The Association for Clinical Oncology (ASCO) analyzed the impact of the MFN model on four immune checkpoint inhibitors (all included in the model) commonly used to treat advanced and metastatic lung and other cancers on the MFN drug list. Based on CMS's projections on forgone care, ASCO estimates that 87,556 years of life will be lost due to loss of access over the duration of the model to these four drugs for lung cancer alone.

CMS describes an available "hardship exemption," where eligibility will be based on year-over-year losses above 25% of total Medicare Part A and Part B payments, including payments for Medicare Part B drugs outside the model and payments for Medicare Part A and Medicare Part B services other than prescription drugs. These losses would be devastating to practices and unsustainable. While CMS states that the agency expects few, if any, providers to have annual losses above this level, the agency also goes on to say, "… and that those who do may be insolvent and therefore unable to obtain retrospective hardship payments." In summary, then, CMS offers a "hardship exemption" that the agency expects few, if any, providers to be eligible for and by the time a provider becomes eligible, insolvency may prevent retrospective hardship payments.

Under the Administrative Procedure Act (APA), CMS is required to publish a notice of the proposed rule in the Federal Register before the provisions of a rule take effect. The Secretary is required to provide for notice of the proposed rule in the Federal Register and provide a period of not less than 60 days for public comment. There are exceptions from the notice and comment requirements and where these exceptions apply, an agency is authorized to dispense with normal rulemaking requirements for good

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cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

CMS cites the COVID-19 pandemic as a basis for requiring immediate action on drug pricing and finds that there is good cause to waive the notice and comment requirements. CMS also finds that delaying implementation of the rule (effective on the date of publication in the Federal Register) and MFN Model is contrary to the public interest for the same reasons that the agency finds good cause to waive prior notice and comment rule making.

FLASCO, supporting ASCO's position that has been already made public strongly disagree with CMS' reasoning and ***urge immediate withdrawal of this interim final rule***. The original "International Pricing Index Model for Medicare Part B Drugs (CMS-5528-P)" proposed rule was submitted to OMB on June 20, 2019 and remained at OMB for approximately 17 months until its clearance by OMB on November 19, 2020. This time period is not at all consistent with any sense of urgency and furthermore as the rule cleared OMB its status was changed from "proposed" to "interim final" rule, thus depriving members of the public and affected stakeholders of any opportunity to review or comment on the rule. This is unconscionable given the hugely negative impact of the rule on Medicare beneficiaries and the providers who care for them. CMS cannot simply make enormously consequential changes to the way Medicare reimburses for Part B drugs that are unrelated to COVID-19 and then use the COVID-19 pandemic as an excuse for these changes.

CMS issued the MFN IFC using its authority to implement demonstration projects granted to the Centers for Medicare and Medicaid Innovation (CMMI). A change in Medicare reimbursement of this size and scope can in no way be considered a "demonstration" – a true demonstration would not be mandatory, require the participation of almost all Part B providers, and be nationwide in scope. The Administration can, through CMMI, test innovative payment and service delivery models to reduce program expenditures "while preserving or enhancing the quality of care furnished to individuals." Denying Medicare beneficiaries access to Part B drugs recommended by their physicians clearly fails to preserve or enhance beneficiary quality of care. In addition, the MFN Model essentially replaces existing Part B drug payment policy determined by statute, and the Administration lacks the authority to supersede previously enacted statutes established by Congress through rulemaking.

FLASCO urges the agency to immediately withdraw this rule and not move ahead with MFN Model implementation.

Sincerely,

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