The US Oncology Network

December 10, 2020

Re: Harm to the patients we serve that will result from the Most Favored Nation rule (the "MFN Rule") issued by the Centers for Medicare & Medicaid Services' Center for Medicare and Medicaid Innovation, 85 Fed. Reg. 76,183 (Nov. 27, 2020).

The undersigned physicians are associated with oncology practices that are part of The US Oncology Network. Collectively, the practices in The US Oncology Network operate more than 480 cancer care centers in 25 states, providing oncology treatment and non-medical support services, such as nutrition, exercise, financial management, and advance care planning, to approximately 625,000 Medicare beneficiaries and roughly 425,000 Medicare fee-for-service (FFS) beneficiaries per year. We submit this letter to inform you of the immediate harm to our ability to serve our patients that will result from the new Medicare reimbursement rates that will take effect on January 1, 2021 under the Most Favored Nation Rule (85 Fed. Reg. 76,183, dated November 27, 2020) (the "MFN Rule").

The MFN Rule affects 38 oncology drugs, many of which we routinely administer at our oncology practices. In 2019, approximately 70% of Medicare recipients receiving Medicare Part B pharmacological treatments across Network practices received one or more of the 38 drugs. Because these drugs are among the most innovative and effective treatments for cancer in our medical judgment, their use is essential to provide the best care to cancer patients. The use of these drugs has contributed to a dramatic increase in life expectancy and remission rates among cancer patients.

The MFN Rule will make it unsustainable for us to continue to provide the same level of care to the same number of Medicare patients we currently serve. Our practices will have no choice but to stop administering drugs on the MFN schedule to numerous Medicare patients.

We typically purchase these drugs under contracts that are negotiated months, or even more than a year, in advance. The contracts fix purchase prices at prevailing market rates, and oncology centers are unlikely to be able to renegotiate the purchase prices before the MFN Rule takes effect on January 1, 2021.

We also maintain sufficient drug inventories to ensure availability for patients undergoing treatment. Thus, our practices already have significant drug inventory on hand to ensure patient care in January 2021, purchased at prevailing market rates. When the clock strikes midnight on New Year's Eve, and the MFN Rule becomes effective, it will immediately and substantially devalue that inventory and result in guaranteed losses.

The drugs affected by the MFN Rule are costly and represent enormous investments on the part of our practices. Because the Medicare reimbursement rates under the MFN Rule are dramatically less than the prices we pay to acquire these drugs, the MFN Rule will impose a significant financial loss every time one of our oncology centers administers any of the 38

oncology drugs to a patient. Our practices may not be able to sustain these staggering losses for even a month, let alone for the years contemplated by the MFN Rule.

The Rule will force patients to make an impossible choice among untenable options: (1) accept alternative, inferior treatment, (2) go elsewhere for treatment, or (3) forgo treatment altogether. Any of these results will detrimentally affect patient care and outcomes.

Alternative Treatment. The oncology drugs that are subject to the MFN Rule are best-in-class, cutting edge treatments that are safer and more effective than other drugs on the market. Some do not have a therapeutic alternative. If the MFN Rule forces practices to substitute alternatives for the listed oncology drugs, patient outcomes will likely be worse. These are the most effective drugs available in the treatment of cancer, prolonging life expectancy and contributing significantly to improved recovery rates. In our collective medical judgment, forgoing use of these drugs will lead to decreased life expectancy for many patients. As medical professionals, we strongly condemn any reimbursement policy that would necessitate administration of inferior treatments to our patients.

Going Elsewhere. Alternatively, our Medicare patients may be forced to go to a 340B hospital or a PPS-exempt cancer center that is exempt from the MFN Rule. This option would also impose unacceptable burdens on our most vulnerable patients. Many of our practices are located in suburban, exurban, or rural areas that are miles from the nearest 340B hospital or PPS-exempt cancer center. If Medicare patients served by our practices were forced to go elsewhere for treatment, they would be facing hours of additional travel time, in the midst of a pandemic, every two weeks for treatment. Moreover, 340B hospitals or PPS-exempt cancer centers do not have the staffing or physical capacity to serve the enormous number of Medicare patients currently treated by our Network practices across the country.

340B hospitals are already under enormous strain as a result of the COVID-19 pandemic. Many are at capacity and having to re-purpose hospital facilities and more importantly staff to take care of COVID-19 patients. During this public health emergency, we do not believe that either 340B hospitals or PPS-exempt cancer centers will be in a position to take on a wave of new patients seeking cancer care. During the COVID-19 pandemic many hospitals have reassigned nursing and physician staff to ICUs and emergency departments. The dislocation of a large collection of cancer patients to alternative sites on short notice during a national health emergency will increase the risk of lapses in appropriate care and medical errors. In addition, transitioning cancer patients to distant sites will not only interrupt their relationship with their primary oncology team but will also jeopardize coordinated care they might receive from multiple co-located community-based physicians involved in managing the patients' co-morbid illnesses such as chronic heart, kidney or pulmonary disease. Establishing appropriate input from these needed medical specialists will be difficult to coordinate in new clinical settings especially with the demands posed by the pandemic. And even if a patient could find an alternative site for treatment, delay in securing treatment at the new facility would worsen patient outcomes.

Forgoing Treatment Altogether. As noted, given the difficulties in transferring the site of care as local oncology centers become unable to provide treatment, there is a real risk that some patients will simply decide to forgo cancer treatment. Asking elderly Medicare beneficiaries to increase travel time for treatment in the midst of a pandemic – sometimes up to hours each way, per treatment – and to bear the increased costs and burdens associated with such travel, will make obtaining treatment even more onerous.

We understand the CMS has recognized that risk as well and projects that the MFN Rule will lead to loss of access to listed oncology drugs for 9% of Medicare patients in the first year, 14% in the second year, and 19% per year in years 3-6. That outcome, in our view, is unacceptable.

We therefore urge you to convey our concerns regarding the devastating impact the MFN Rule will have on our oncology practices and, more importantly, on the ability of our Medicare patients to receive proper medical care.

Sincerely,

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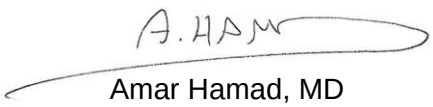

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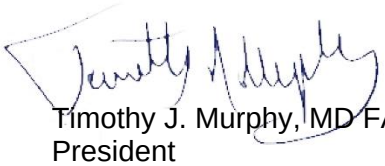

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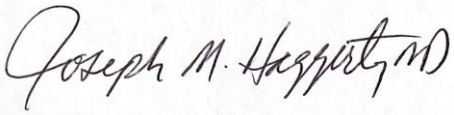

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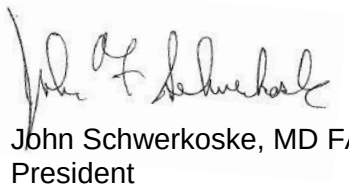

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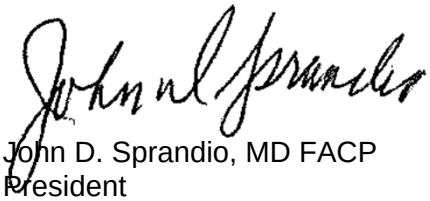

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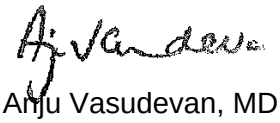

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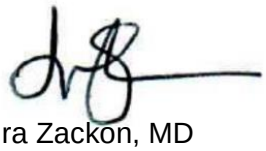

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