**STATEMENT ON THE MOST FAVORED NATIONAL MODEL**
**May 4, 2021**

The undersigned organizations, representing a diverse group of stakeholders in the urologic community, have developed this joint statement on the regulatory policy known as the Most Favored Nation (MFN) Model Interim Final Rule with Comment Period [CMS–5528–IFC]. While implementation of this model has been blocked by the federal courts, we feel it is necessary, and in the best interest of patients, to publicly state our concerns in the hopes that our national leaders will act to address them.

The undersigned organizations support the overall goal of lowering prescription drug prices and ensuring patients can afford medically necessary drugs, but believe the MFN Model as currently structured fails in this attempt. While we understand the desire to test the effectiveness of aligning the country's drug prices with those abroad, we are greatly concerned that the MFN Model will negatively affect patient access to medically appropriate urologic care and treatments as well as the ability of urologists and other providers across the country to provide high quality care.

**THE MFN MODEL MAY NEGATIVELY AFFECT PATIENT ACCESS TO MEDICALLY APPROPRIATE UROLOGIC CARE.**

As currently designed, the MFN Model includes multiple drugs essential to the practice of oncologic urology and functional urology, which could become more difficult for patients to access. Those listed drugs include treatments for non-muscle invasive bladder cancer (NMIBC), prostate cancer and advanced prostate cancer, overactive bladder (OAB), and bone loss for cancer patients. In 2020, patients were diagnosed with more than 81,000 new cases of bladder cancer and 191,930 new cases of prostate cancer. These cancers are more likely to develop in those 65 and above, making access to these drugs even more essential to the vulnerable Medicare population. OAB affects as many as 30 percent of men and 40 percent of women across the country, and again is more likely to affect those over the age of 65.

The Centers for Medicare & Medicaid Services' Office of the Actuary (OACT) has identified the MFN as contributing to a significant reduction in patient access to necessary medications placed on the MFN pricing list. One year into the seven-year phased-in program, nearly one in ten beneficiaries whose providers no longer offer access to the MFN listed drugs could lose access to their medically necessary medications completely. By year three, OACT estimates nearly one in five beneficiaries could lose all access. Patients with urologic cancers treated by our members are especially vulnerable should the MFN Model delay or limit their access to medically prescribed treatments. As a result of delayed treatments, patients with these types of cancers may see their conditions deteriorate. We are concerned limited access may result in higher rates of hospitalizations, which could further burden a healthcare system that will likely be in a year's long recovery post-pandemic and increased mortality rates overall.

The Centers for Disease Control and Prevention has explored the effects of non-adherence to prescribed medications, of which barriers to obtaining medication play a factor. Non-adherence to prescription drugs causes 30 to 50 percent of treatment failures and 125,000 deaths per year in the United States. As the text of the MFN rule acknowledges, "a portion of the [Medicare] savings is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization." This decrease in utilization following the implementation of the MFN Model is likely to result in an increase in medication non-adherence as patients experience greater barriers to treatment– potentially leading to a rise in treatment failures and deaths.

**THE MFN MODEL MAY NEGATIVELY AFFECT THE ABILITY OF UROLOGISTS AND OTHER PROVIDERS ACROSS THE COUNTRY TO PROVIDE HIGH QUALITY CARE.**

The undersigned organizations believe the rule may adversely affect the ability of urology practices to provide high quality care. Urologists across the country already are dealing with ongoing drug shortages, which in turn has caused some providers to adjust their course of care due to lack of access. As an example, Bacillus Calmette-Guerin (BCG), a standard treatment option for patients with NMIBC, has been in shortage since 2016 due to an increase in worldwide demand. With this shortage, urologists have had to adjust their management approaches to treat their patients. Another NMICB drug demonstrated to reduce the 10-year incidences of tumor recurrence and used to treat those who are unresponsive to BCG is part of the MFN Model, raising additional concerns about adequate access to treatments for NMIBC and for the well-being of patients. The undersigned organizations believe the MFN Model may create a heightened burden on urologists' ability to treat their patients with the highest quality drugs.

Additionally, urologists across the country maintain inventories of the treatments commonly administered as part of their practice. These inventories are acquired in advance of treatment and stored according to manufacturer's recommendations until administration. The MFN Model actively discourages the practice of stocking inventory by injecting uncertainty into a necessary urology business practice. The potential for a treatment to be added to the MFN pricing list will give many providers, including urologists, pause before purchasing and holding treatments in inventory. An inventoried item added to the MFN list is devalued instantly, regardless of the price paid by the urologist, and that provider may be unable to recoup their cost. The effects of this change would be far reaching; smaller practices, including those in rural areas, may be unable to maintain any stock. Even large practices may be unwilling to carry higher cost treatments for fear of a major loss in revenue.

**THE UNDERSIGNED ORGANIZATIONS REQUEST THE MFN MODEL BE WITHDRAWN, AND ANY MODEL DESIGNED TO LOWER PART B DRUG PRICES BE ISSUED UNDER STANDARD NOTICE AND COMMENT RULEMAKING.**

In closing, the undersigned reiterates our concerns with the potential loss of patient access to physician prescribed treatments. The loss of access to one out of five beneficiaries is not

justified by the potential savings to the Medicare Part B program. Additionally, and as the rule notes, patients may not be able to receive their treatments from their regular provider and may need to seek their treatments elsewhere, or not at all. For these reasons, we ask that the MFN Model be withdrawn and any future model designed to reduce Part B drug prices be issued with a standard notice and comment period.

The undersigned organizations welcome the opportunity to work with lawmakers to explore alternatives to control drug prices while protecting patient access to medically appropriate therapies. If there are any further questions or concerns, please reach out to Raymond Wezik, the American Urological Association's Policy & Advocacy Director, at rwezik@auanet.org.

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