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December 14, 2020

RE: CMS-5528-IFC, "Most Favored Nation Model" interim final rule with comment period

Dear Administrator Verma:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of a group of state and regional professional rheumatology societies throughout the country formed to advocate for excellence in rheumatologic disease care and to ensure access to the highest quality care for the management of rheumatologic and musculoskeletal diseases. Our nationwide coalition serves practicing rheumatologists in charge of patient care for these illnesses.

We urge you to delay implementation of the Most Favored Nation Model ("MFN Model") as described in the above-referenced interim final rule with comment period ("the rule"). Practicing rheumatologists are keenly aware of the rising out-of-pocket burdens on our patients. Given that most patients have Part B wraparound coverage, the drugs covered by Part B provide a more accessible option for patients who cannot afford the large out-of-pocket cost exposures of Part D. The MFN Model, ironically, will significantly reduce patient access to the more accessible option, while leaving intact the large out-of-pocket burdens of Part D.

We have several concerns with the MFN Model, as outlined in detail herein.

First and most importantly, the MFN Model will curtail patients' ability to access Part B drugs – *as CMS explicitly acknowledges in the rule*. CMS states that participants may "choose" not to provide MFN Model drugs, which belies the reality that many participants will not have the choice. It is a foundational principle of budgeting that, if practices cannot acquire medicines for a price that is lower than the reimbursement, they will not be able to provide the medicines for long. When that occurs, CMS acknowledges that "beneficiaries may experience access to care impacts," including finding other providers (with the existing shortage of rheumatologists, this will be difficult), traveling to seek care, receiving an alternative therapy "that may have lower efficacy or greater risks," or even "postponing or forgoing treatment." This is not a gamble we can take with the vulnerable beneficiaries who rely on these medicines, particularly since the Model is nationwide and mandatory. Many practices have already started to curtail ordering Part B medications for Medicare patients because of the potential losses starting in January, which means that many patients will be without treatment as early as the first week of January.

While any chronic illness is serious, infusible medicines generally treat severe, debilitating diseases, such as rheumatoid arthritis, where even a few weeks of delay can result in severe pain and irreversible joint damage. This loss of access is no theoretical concern: CMS explicitly acknowledges that a portion of the Model's savings "is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization." This means that a portion of the estimated savings are not the result of reduced drug prices, but of reduced drug spending due to denial of access.

While there is no good time to deny vulnerable beneficiaries access to their medicines, the timing of this Model is *exceptionally* bad. As noted above, most Part B beneficiaries have wraparound coverage. For those who do not, the Model should reduce out-of-pocket cost-sharing. This means that CMS' prediction that beneficiaries will not access their drugs cannot be due to cost. Rather, it would be due to a loss of accessible infusion sites. At a time when the only two COVID treatments we have are infusible antibody treatments, it seems absurd that CMS is enthusiastically launching a Model that would reduce our nation's infusion capacity and consolidate larger numbers of COVID-positive and immune-compromised patients into hospital outpatient departments.

Second, the rollout of the Model via interim final rule without any meaningful opportunity for comment violates the Administrative Procedure Act (APA). The Model's serious procedural shortcomings are perhaps best evidenced by the fact that the comment period ends on January 26, 2021, almost a month after the Model begins on January 1, 2021. At best, CMS seems to view the commenting period as an annoying technicality to be checked off, not the opportunity for meaningful and actionable input contemplated by the APA. It is important to note that the MFN Model is neither the substantive nor the procedural evolution of the previously proposed International Pricing Index. As such, affected stakeholders have no meaningful opportunity to comment on the Model, including feedback on logistical rollout issues that could prevent or at least ameliorate beneficiary access issues.

Remarkably, the procedural issues do not end there. The MFN Model, despite its name, is not in fact a "model" by any reasonable definition of the word. It is a Medicare program change. The MFN Model is nationwide, lasts for seven years, affects fifty Part B medicines, has no opportunity for exemption in the first year, and auto-drafts participants via the usual claim submission process. Since the entire Part B program is implicated, all beneficiaries who require any of the fifty included drugs are automatically drafted into the Model. There is no control group. The reason this program change must masquerade as a "model" administered via the Innovation Center is that CMS bypasses the statute establishing Part B payment. Yet simply calling something a "model" does not make it so; functionally, the so-called MFN Model is a Medicare program change.

To justify rushing through this Part B overhaul in a mere month, the Administration claims that high drug prices have taken on a new urgency for Medicare beneficiaries during the pandemic. This claim is specious, since, unlike the large numbers of individuals who have lost their employer-

sponsored coverage this year, Medicare beneficiaries have not lost their health coverage due to the pandemic. Additionally, as noted above, 81% of Part B beneficiaries have wraparound coverage and are thus among the few Americans actually protected from high out-of-pocket drug costs. Moreover, none of the fifty included products are for the treatment of COVID; indeed, any current or future product approved for COVID via emergency use authorization by the Food and Drug Administration is categorically exempted from the Model. There is no link to the pandemic here.

Third, the Model's expected outcome rests entirely on the hope that pharmaceutical manufacturers will lower their prices down to the 75%/25% average sales price/MFN price blend in the next three weeks. If they cannot, physician practices will absorb the financial losses. For many, this will simply be impossible. As stated earlier, we have heard from many rheumatologists who feel that they must put their ordering on hold, until they have certainty on reimbursement come January. Additionally, as patients learn they may not be able to get their treatments as scheduled in the coming months, the Model will create uncertainty and instability at a time when both of these are sorely needed by everyone, particularly our seniors with chronic diseases. This, in and of itself, is enough to cause flares in systemic inflammatory diseases. The MFN Model is essentially a gamble that the market will respond quickly enough; a gamble that has as its stakes Medicare beneficiaries in need of medicine and an already fragile healthcare infrastructure.

After we continue to review the Model, we may file additional comments. However, given the truncated timeline to provide any input at all, we wanted to write you as soon as possible to request that you ***delay implementation of the Model***, so that we can work on addressing these serious issues. Lowering drug prices is a critically important endeavor and one we strongly support, but the concept of lowering Medicare's drug spending by simply denying beneficiaries access must be rejected outright.

Thank you for your consideration of these comments. If you require additional information, please do not hesitate to contact us.

Sincerely,

Alabama Society for the Rheumatic Diseases
Alaska Rheumatology Alliance
Arizona United Rheumatology Alliance
Arkansas Rheumatology Association
California Rheumatology Alliance
Coalition of State Rheumatology Organizations
Colorado Rheumatology Association
Connecticut Rheumatology Association
Florida Rheumatology Society
Georgia Society of Rheumatology
Hawaii Rheumatology Society

Kentuckiana Rheumatology Alliance
Massachusetts, Maine, and New Hampshire Rheumatology Association
Michigan Rheumatism Society
Midwest Rheumatology Association
Mississippi Arthritis and Rheumatism Society
Nebraska Rheumatology Society
New Jersey Rheumatology Association
New York Rheumatology Society
North Carolina Rheumatology Association
Ohio Association of Rheumatology
Oregon Rheumatology Alliance
Pennsylvania Rheumatology Association
Rheumatology Alliance of Louisiana
Rheumatology Association of Iowa
Rheumatology Association of Minnesota and the Dakotas
Rheumatology Association of Nevada
Rheumatology Society of New Mexico
South Carolina Rheumatism Society
Tennessee Rheumatology Society
Virginia Society of Rheumatologists
Washington Rheumatology Alliance
West Virginia Rheumatology Society
Wisconsin Rheumatology Association