December 24, 2018

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM)

Dear Administrator Verma,

On behalf of the more than eight million Americans living with psoriasis and psoriatic arthritis, the National Psoriasis Foundation (NPF) appreciates the opportunity to comment on Medicare Program; International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM) advanced notice of proposed rule making.

As the patient advocacy organization for the psoriatic disease community for more than 50 years, the NPF is keenly aware of the improvements in health outcomes that have resulted from advances in treatment innovation. Our community is fortunate in that there are several therapies approved for the treatment of psoriatic disease including biologics, systemic treatments, small molecule medicines, phototherapy, and topical treatments. The variety of these treatment options means that patients receive their Medicare drug coverage through both Part B and Part D. Therefore, the NPF remains committed to ensuring Medicare beneficiaries with psoriasis and psoriatic arthritis have access to the full range of treatments and therapies necessary to successfully manage their disease. Understanding that cost can be one of the biggest barriers to this critical access, we commend the Administration for its focus on reducing the financial burden for our community. Upon review of this advanced notice of proposed rule making, we would like to highlight some areas that we believe require further detail and explanation as this rule making process advances.

Primarily, the psoriatic disease community would appreciate more information on the negotiation tools that will be permitted by the new vendors in this Part B demonstration. We appreciate the intention to lower costs, particularly out of pocket costs for Medicare beneficiaries. However, we understand that in order to accomplish this, vendors will need some leverage for negotiation. We are concerned that this leverage will include the ability to create formularies or implement overly burdensome utilization management techniques. As heterogeneous chronic immune-mediated diseases, psoriasis and psoriatic arthritis require sophisticated medical care and tailored treatment plans. Treatments that work for one person may not be effective for others, and a drug that works well for a person may see its efficacy diminish over time. Given this reality, many of our patients cycle through a variety of accepted treatment options before finding the most effective therapies, or combination of therapies; a situation that necessitates access to a wide array of approved treatments.
We are concerned by the prospect of this policy leading to unnecessary and potentially harmful barriers to access in the form of burdensome utilization management tools. In the commercial markets and Medicare Part D, our patients already face disproportionately high barriers to access, and it is on the rise. In the employer market where only 18 percent of health plans relied on both step therapy and prior authorization in 2015, that increased to 56 percent in 2017. We strongly caution against implementing any Medicare Part B policy changes that aim to reduce costs by reducing access, such as allowing for more restrictive formularies or increasing the ability to apply prior authorization or step therapy. The advanced notice of proposed rule making references the plan to give physicians the option of working with multiple drug vendors. We encourage CMS to structure the demonstration to ensure that physicians have this flexibility, which should make it easier for them to access the drugs that they need in a timely manner. When the proposed rule is released, we would appreciate additional information on how patient access to treatments will be protected during the proposed demonstration.

Additionally, we caution the Administration to ensure this proposed reform does not disproportionately impact psoriatic disease patients living in small or rural communities. For these patients, the challenges in accessing the most appropriate therapy may be even more complex than for most, particularly given the challenges that these patients may face in finding a local dermatologist or rheumatologist, the physicians best qualified to provide care to people with psoriatic disease. Changes to reimbursement rates that are meant to reduce costs may be a barrier for providers in these communities that offer beneficiaries access to needed medications. This may be particularly true if reimbursement rates are based on physician specialty. We urge CMS to make considerations for patients in these areas and to include rural areas in the proposed demonstration, to ensure that they do not see an outsized impact from this policy.

As stated above, we commend the Administration’s focus on reducing patient costs in the drug market. While the Part B system is structured to include a 20 percent cost sharing requirement for patients, we are well aware that, in practice, most patients do not bear that burden. Data shows that only 14 percent of traditional Medicare beneficiaries do not have supplemental coverage, and of those with additional coverage many have taken advantage of an increasing number of plans that offer a $0 cost sharing for Part B therapies. Therefore, we would appreciate additional details on how patients will share in the cost savings of this new demonstration program. We want to ensure that any potential savings are shared with beneficiaries and not simply absorbed by the new vendor middlemen in the system. We look forward to additional details in the forthcoming proposed rule.

Finally, we would also appreciate more information on the impact of this proposal on access to Part D medications. In the Part D program, biologics used to treat psoriasis and psoriatic arthritis are routinely placed on specialty tiers of plan formularies, resulting in an average coinsurance rate of more than 30 percent of the drug costs and no access to tiering exceptions that are provided to other formulary tiers. A recent NPF Advocacy survey showed that nearly one in three Medicare beneficiaries who take a biologic report a monthly out-of-pocket cost of more than $200. Due to this burden, a full half of Medicare beneficiaries with psoriatic disease reported financial strain due to the cost of accessing biologics. In fact, a study of Medicare beneficiaries with psoriasis showed that those without access to the Low-Income Subsidy (LIS) program (or ExtraHelp) were 70% less likely to receive a biologic as a consequence of the inability to pay. Therefore, many members of our community who struggle with costs rely on Part B medications to treat their psoriatic disease. We are concerned that policy reforms that restrict access to Part B medications could force members of our community to take a more expensive drug in the Part D program, potentially further diminishing their ability to properly treat their condition. In the upcoming proposed rule, we would appreciate additional information on how this proposal could impact the Part D program and access to medications for therapy classes that span both programs.

While the NPF commends CMS on its interest in improving patients’ access to therapeutic treatments and that drug coverage options are affordable and accessible, we stress that proposed changes should not inhibit the ability of Medicare beneficiaries to access the most appropriate therapies that address their specific health care needs. We

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appreciate your consideration of our comments and look forward to additional details in these areas as the rule making process advances. If you or your colleagues have any questions, please feel free to contact me at pstone@psoriasis.org or 503.546.5562.

Sincerely,

Patrick Stone
Vice President, Government Relations & Advocacy