November 16, 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 and Medicaid Programs; Regulation To Require Drug Pricing Transparency (CMS-4187-P)

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 the Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency proposed rule (CMS-4187-P).

The NPF remains committed to ensuring Medicare and Medicaid 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 burden for our community. We applaud the Department’s emphasis on transparency and providing health care consumers with the information they need to make better informed choices, and the psoriatic disease community stands to see a large impact from this proposed rule. A recent analysis by Kaiser Health News showed that four of the top ten most advertised drugs were used to treat psoriasis or psoriatic arthritis, more than any other disease state included in the analysis. Therefore, we appreciate your attention to our comments on ways to strengthen this proposed policy to ensure the information provided to patients is meaningful as they make important decisions about their health and health care.

As the proposed rule states, “price transparency is a necessary element of an efficient market that allows consumers to make informed decisions when presented with relevant information.” Patients in our community are fortunate in that, although there is not yet a cure for psoriasis or psoriatic arthritis, there are many treatment options available including biologics, topical treatments, and light therapy. When assessing treatment options, we encourage patients to weigh cost as one of many variables to consider. However, as the proposed rule goes on to clarify, there are several aspects of the health care marketplace that make this aim for transparency imperfect. Third party payment, through private and public insurers, causes sizeable distortions to the market and obscures meaningful prices from consumers. This limits the traditional role that price plays in other consumer markets. Furthermore, the variability across insurers and pharmacy benefit managers (PBMs) creates an additional barrier to transparency. As the proposed rule highlights, “A PBM could have ten different clients with ten different benefit designs and it would be possible that an employee from each client could get
the exact same product and all ten could pay a different price.” This adds a challenge of determining which price is most relevant to consumers because, as clearly outlined in the proposal, prices vary widely in the health care market.

Patients' abilities to assess treatment options are further complicated by the different formulary designs and utilization management policies across PBMs and third party payers. Unfortunately, often times these formulary and utilization management policies, like prior authorization and step therapy, are based on rebates and manufacturer concessions and not on clinical practice or guidelines. This means patients with psoriatic disease and their physicians often have their choice in drugs dictated by out-of-pocket and other cost burdens rather than the efficacy of the drug. A recent study published in Health Affairs demonstrates the wide discrepancy across step therapy protocols in commercial insurance markets as they relate to indications approved by the Food and Drug Administration. The study showed that of 302 drug-indication pairs reviewed, only 16 percent were covered the same way by all health plans. Additionally, more than one-third of the health plans’ coverage decisions were considered more restrictive than the FDA indication. As the authors note, part of this discrepancy is due to the different discounts that are negotiated between manufacturers and payers. The authors also stress that these coverage decisions should be evidence-based and should be transparent for consumers. This study highlights how opaque these coverage decisions can be and the large role that nonpublic negotiations play in establishing access to therapies for those with psoriasis or psoriatic arthritis. Because of this impact, this process needs to be better understood in order for price transparency to have its intended effect.

We also share the Administration’s concerns about the potential unintended consequences this new policy could have on disease awareness and deterring patients from treating appropriately. The proposed rule highlights that the list price could intimidate consumers as they might not realize that the price in the ad does not properly reflect what they have to pay. This presents a particular concern for our community, where many people are already under-treating their disease. Data from a 2015 annual NPF survey showed that nearly 50 percent of psoriasis and psoriatic arthritis patients do not properly treat to the level of severity of their disease. While this proposed policy could exacerbate this trend, we are particularly concerned about the impact on rural and underserved communities, where patients already face sizeable access challenges that include access to specialists such as dermatologists and rheumatologist and the ability to meet out-of-pocket healthcare expenditures.

**Recommendations to Improve the Proposal**

With this context in mind, the NPF recommends the following refinements to the proposed rule to ensure the information provided to consumers enables better health care choices and doesn’t further distort treatment choice decisions for the psoriatic disease community.

**Improving Cost Estimate Accuracy**

We encourage CMS to consider requiring not just the list price but also additional context on what patients can actually expect to pay in out-of-pocket costs. As stated above, insurance plan design and payer negotiation results in a wide variability in what consumers pay for medications. This means the list price doesn’t provide a complete picture and could actually be counterproductive in scaring people away from seeking treatment. If CMS is going to require disclosure of the list price, we urge that this information be placed in the context of average or general patient costs. While coinsurance rates can vary widely in the commercial market, CMS has a clearer picture of the coinsurance rates in the Medicare system. Since the benefit design must align with statutory requirements, CMS could reasonably calculate the average coinsurance rate for Medicare beneficiaries. Therefore, we encourage CMS to consider including a formulary or calculation alongside the list
price required in the ads. This calculation will help provide more meaningful basis of comparison for patients and could help mitigate some of the concerns of negative unintended consequences.

**Drug Price Counseling**
We support expanding the role of health care providers in counseling patients on treatment costs. In many instances, prescribers are best positioned to help patients understand the role of costs in treatment plan choices. Providers can help educate patients about their health insurance plan, out-of-pocket costs, and the pros or cons of various treatment choices. We appreciate the Administration’s recognition of the importance of these kinds of conversations and hope CMS moves forward with developing a payment code for drug price counseling. However, these conversations will be most valuable if prescribers have real time data on patients’ insurance plans, deductible status, out-of-pocket burden, and drug price. Without these key components, physicians will be left with an incomplete ability to truly counsel patients on the role cost should play in their treatment deliberations. We urge the Administration to ensure that this new code is developed with those considerations in mind, particularly the provider time that would be needed to review such data and provide a patient with an informed recommendation.

**Plan Selection Tools**
We also support moves to create intelligent plan selection tools. Providing patients with recommendations of the best plan choices that consider their health needs will lead to a better match between consumers and health plans. This will help beneficiaries take some of the guess work out of open enrollment decisions and provide valuable information that consumers need to make smart choices about their health insurance.

**Requirements for Other Advertising Media**
Treatment for psoriatic disease is the focus of significant advertising efforts. In 2017 alone one manufacturer of a leading biologic spent $317 million advertising that singular product. Therefore, we urge the Department to expand these transparency efforts beyond television advertising. Other media formats, including digital media, play a dominant role in how members of our society gain information. In fact, in 2017 digital ad spending reached $208 billion globally, surpassing TV spending by just over $30 billion. By only focusing this rule on TV ads, drug manufacturers may share inconsistent information across different mediums or provide only certain consumers with this information. Expanding these efforts will help address the system as a whole and ensure that manufacturers don’t simply shift advertising strategies to maneuver around the new rules.

**Course of Treatment Definition**
We would appreciate additional information on how the Administration plans to define “typical course of treatment” when determining which price needs to be shared with consumers. Treatment regimens can vary widely across therapies for psoriasis and psoriatic arthritis. Different medications require different periods between doses. The level of dose and cost can also change depending on whether a patient is new to a medication (and needs a loading dose), the patient’s weight or if the medication is used to maintain a health status. Instead of focusing on “typical cost of treatment,” we encourage the Administration to consider requiring the disclosure of an average yearly cost divided into a monthly increment. This could smooth variations attributable to dose timing and other unique aspects of therapies while still providing meaningful information to consumers.

**Considering Rebates in Cost Estimates**
Lastly, the proposed rule states that the list price is particularly relevant due to the growing percentage of patients who pay a coinsurance, not a flat copay, for their medications. As the NPF has previously suggested to the Administration, it is unfair for patients to pay that coinsurance rate based off the list price given all of the rebates and other price concessions that are negotiated between manufacturers and payers. Even the Institute
for Clinical and Economic Review (ICER) called out this unfairness in the system in a 2016 report on *Targeted Immunomodulators for the Treatment of Moderate-to-Severe Plaque Psoriasis: Effectiveness and Value*. The report highlights how, increasingly, psoriatic disease patients face coinsurance instead of copay rates, particularly for higher-cost biologic treatments. As ICER notes, “higher out-of-pocket costs put patients at high risk of coverage loss, bankruptcy, and inability to access effective treatment necessary to control a chronic disease.” The report demonstrates that even though rebates and manufacturer discounts are substantially more for psoriasis drugs, patient out-of-pocket payments are still based on the list price for these medications. To address this, ICER argues that “co-payment and/or co-insurance for therapies should be based on prices net of discounts and rebates instead of list price.” This would allow patients to share in savings from cost-effective treatment pathways, especially if part of a step therapy protocol. We believe this policy change could lead to improved access, increased medication adherence, and improved health outcomes and we are willing to serve as a resource as CMS evaluates options for implementation.

We appreciate your consideration of our comments. 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

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2. CMS-4187-P. Page 52790
3. CMS-4187-P. Page 52790
8. Ibid.