



Our Mission: To drive efforts to cure psoriatic disease and improve the lives of those affected.

April 8, 2019

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: HHS Removal of Safe Harbor Protections for Rebates Involving Pharmaceuticals (42 CFR Part 1001)

Dear Secretary Azar,

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 Department of Health and Human Services (HHS) Removal of Safe Harbor Protections for Rebates Involving Pharmaceuticals (42 CFR Part 1001). 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. Therefore, the NPF remains committed to ensuring beneficiaries with psoriasis and psoriatic arthritis have access to the full range of treatments and therapies necessary to successfully manage their disease.

The current framework of the drug rebate system is not managed in a way that is beneficial to patients, particularly those with chronic illnesses like psoriasis and psoriatic arthritis who often have high out-of-pocket costs to manage their disease. As currently constructed, the rebate system drives our patients' treatment costs higher and higher annually and ultimately limits psoriatic patients from access to costly life-changing drugs. Earlier this year, the secretary highlighted a story about a patient with a chronic disease whose experience sounded much like those of our community. The woman was facing financial struggles to secure the treatments needed to manage her chronic disease stating:

“The sticker price for a year’s treatment on this drug runs into the tens of thousands of dollars. Sue was told that her out-of-pocket costs for the drug would be \$,7,200 a year on her Medicare part D plan. When she heard that price, she said she just broke down and cried. She simply couldn’t afford it.”¹

Unfortunately this is not an isolated incident for patients with psoriatic disease. On a daily-basis, too many patients are attempting to manage their condition by navigating rising drug prices and out-of-pocket costs. According to a recent study, the annual treatment costs for tumor necrosis factor [TNF] inhibitor drugs, one of the leading types of treatments for those with psoriatic disease, increased by

¹ <https://bipartisanpolicy.org/events/a-keynote-address-from-hhs-secretary-alex-m-azar-ii/>

144% from \$15,809 per year in 2009 to more than \$38,000 in 2016.² Bearing in mind the connection between drug prices and out of pocket costs, it is easy to understand how individuals with chronic diseases are challenged in managing their disease. Drug manufacturers often blame the current rebate system for driving increases in list price. As one pharmaceutical executive outlined, “[we retain about 50% of the list price] the rest goes to subsidize profitability of pharmacy benefit managers (PBMs), insurance companies and frankly premiums of those that are healthy.”³ While we do not agree entirely that rebates are to blame for the difference between list price and net price, we acknowledge the complexities of the problem and we believe the Administration’s proposal will make it more difficult for manufacturers to defend increases in list prices and lead to lower list prices.

We are pleased the Administration recognizes that “under the current rebate-based system, beneficiaries may not receive the benefits of reduced prices and costs that other parties do”⁴ and that “the goal of this policy is to lower out-of-pocket costs for consumers...”⁵. Unfortunately, patients with psoriatic disease are all too familiar with the burden that comes with the high cost of treatment, which can result in reduced access, outcomes and overall well-being. A 2018 NPF Advocacy survey of NPF members found that nearly 50 percent of psoriasis and psoriatic arthritis patients, many of whom live on a fixed income, experienced financial strain due to the cost of their treatment. Equally alarming, almost one in four patients with psoriatic disease spend more than \$150 per month in out-of-pocket costs to access treatment needed to manage their chronic condition. We recognize and studies show that patient adherence decreases as out-of-pocket costs rise.⁶ In fact, just a \$10 increase in expected out-of-pocket costs results in a nearly 5 percent drop in patient adherence.⁷

Removal of Rebate Safe Harbor

We agree with the Administration’s position that the widespread use of rebates has become a problem and has resulted in increased costs for patients and impeded their ability to access quality health care⁸. According to a recent report, between 2010 and 2015, the amount of rebates received by Medicare Part D sponsors and PBMs increased nearly 24 percent annually and “much faster than the overall growth in gross drug costs in the same time period”⁹. We also believe that by eliminating the safe harbor for rebates in the Medicare Part D space that this prohibition combined with allowing their use at the point of sale, may lead to lower list prices for patients and greater patient adherence to prescribed medicines. However, we are concerned by the Administration’s assertion that by solely eliminating rebates manufacturers will be incentivized to lower list prices¹⁰. In fact, the CMS Office of the Actuary (CMS OAC) predicts that manufacturers will retain 15 percent of existing Medicare Part D rebates and “rather

² San-Juan-Rodriguez A, Prokopovich MV, Shrank WH,, Good CB, Hernandez I. Assessment of price changes of existing tumor necrosis factor inhibitors after the market entry of competitors [published online February 18, 2018]. *JAMA IntMed*. doi:10.1001/jamainternmed.2018.7656.

³ <https://www.wsj.com/articles/flip-the-script-drugmakers-blame-middlemen-for-price-hikes-11549364401>

⁴ Rule page 2342

⁵ Rule Page 2352

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/>

⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/>

⁸ Rule Page 2351

⁹ <http://us.milliman.com/insight/2019/Changing-the-rebate-game-A-primer-on-the-HHS-proposed-rule-to-shift-drug-rebates-to-POS/>

¹⁰ Rule Page 2352

than reducing list prices and offering discounts to achieve current net prices, the expected behavior is to reduce future price increases.”¹¹ Additionally, the CMS OAC predicts that only 25 percent of the current rebate would be dedicated by manufacturers to lower list prices for patients.

While we agree with the elimination of the safe harbor for rebates and the intent to lower drug prices and out-of-pocket costs across the board, we are concerned that manufacturers will not substantially lower list prices and reduce future price increases. We understand the administration is seeking alternative pathways to lower list prices and reduce future price increases and we look forward to working with you on reducing out-of-pocket costs for patients.

Establish a Safe Harbor for Point-of-Sale Discounts

We commend HHS for proposing a new safe harbor for point-of-sale reductions or up-front discounts (Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products). We believe this will provide greater transparency for patients with chronic illnesses, advances patient adherence to treatment regimens, provides patients with more significant and direct savings than the current model and results in better health outcomes overall. As a recent report by the Institute for Clinical and Economic Review (ICER) explains, “what is indisputable is that eliminating rebates and moving to upfront discounts would have the potential to move the entire drug purchasing, negotiating, coverage, and delivery system towards greater transparency and a firmer foundation on true value.”¹² Furthermore, ICER explains that this proposal will significantly limit gaming in drug pricing by moving away from a “rebate economy” and toward a “system based on upfront discounts plan sponsors and payers could shift their selection of PBMs away from looking predominately at rebate levels, and toward overall quality and value.”¹³

While we believe the proposal is a step in the right direction and could tremendously benefit patients with chronic illnesses like psoriatic disease lower their out-of-pocket costs and improve health outcomes, we are concerned that it could encourage manufacturers to offer limited discounts. As outlined in the proposal, “reduction in price must be completely reflected in the price the pharmacy charges to the beneficiary at the point of sale”.¹⁴ By itself, this piece of the proposal is a net positive and will greatly increase transparency and affordability of drugs for patients with chronic illnesses. However, manufacturers may limit discounts at the point of sale, which could ultimately lead to higher out-of-pocket costs for patients. As explained in a recent report, “the implicit transparency in upfront discounts is also viewed as problematic, potentially leading manufacturers to set single discount levels for all payers that would increase overall costs.”¹⁵ With this in mind, we encourage HHS to make meaningful revisions to the point-of-sale discount proposal that would set parameters for discounts that manufacturers would be required to offer as upfront discounts. We believe explicit guidelines on point-of-sale discounts would reduce out-of-pocket costs and overall cost increases in the market, advance patient adherence to medication and lead to better health outcomes for patients with psoriasis and psoriatic arthritis.

¹¹ Rule Page 2356

¹² <https://icer-review.org/wp-content/uploads/2019/03/March-2019-ICER-OHE-White-Paper-on-Rebates-Final.pdf>

¹³ <https://icer-review.org/wp-content/uploads/2019/03/March-2019-ICER-OHE-White-Paper-on-Rebates-Final.pdf>

¹⁴ Rule Page 2349

¹⁵ <https://icer-review.org/wp-content/uploads/2019/03/March-2019-ICER-OHE-White-Paper-on-Rebates-Final.pdf>

Additionally, we are concerned that this proposal is lacking sufficient resources to educate patients on the savings that they may see at the pharmacy counter. Therefore, we encourage HHS to clarify how the agency intends to engage with patients, patient groups, providers and plans to educate the public on these changes. We also would encourage HHS to update standards for e-prescribing to include a real-time benefit tool requirement on Part D sponsors that would provide prescribers with complete, accurate, timely and clinically appropriate patient-specific, real-time information on drug cost, formulary alternatives or utilization management requirements. We urge the Agency to not only encourage, but to require or incentivize plans to use these systems to promote drug-cost transparency, particularly the beneficiary's out-of-pocket cost information. Any information about price increases or alternative treatments – either to patients in EOBs or providers at the point of care – must always focus on the impact of a patient's out-of-pocket costs. Broad information is of little use in furthering transparency unless it reflects rebates and price concessions, savings passed on to the patient, and net patient copayment increase or decrease associated with the prescribed treatment and/or its lower-cost alternatives.

Placement of Biosimilars on Formulary Tiers

We commend the Administration for recognizing that “the use of rebates creates a financial incentive to make formulary decisions based on rebate potential, not the quality or effectiveness of a drug.”¹⁶

While many individuals living with psoriatic disease experience high out-of-pocket costs when accessing care, it is especially acute for Medicare beneficiaries with Part D coverage. 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 of Medicare beneficiaries found that nearly one in three 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. Another 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.¹⁷

The ability of patients to assess treatment options are further complicated by the different formulary designs and utilization management policies across PBMs and third-party payers. Unfortunately, these formulary and utilization management policies, like prior authorization and step therapy, are often based on rebates and manufacturer concessions rather than on clinical practice standards or care 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. This is particularly alarming for patients with psoriasis and psoriatic arthritis who are frequently at risk of developing additional chronic conditions as a result of their psoriatic disease diagnosis. As guidelines published in 2019 by the National Psoriasis Foundation (NPF) and the American Academy of Dermatology (AAD) indicate, individuals with psoriatic disease are at a heightened risk of developing a

¹⁶ Rule Page 2342

¹⁷ Takeshita, Junko et al. Psoriasis in the US Medicare Population: Prevalence, Treatment, and Factors Associated with Biologic Use. *Journal of Investigative Dermatology*. 2015. Dec; 135(12), 2955 – 2963

number of comorbid conditions including cardiovascular disease and stroke, diabetes and hypertension, as well as depression and anxiety.¹⁸

As stated in the proposed rule, “the current rebate framework may deter plans or their PBMs from placing lower cost, therapeutically equivalent drugs on their formularies or may incentivize these entities to give preferred formulary placement to a higher-cost drug that carries a higher associated rebate.”¹⁹ We share the Administration’s concern that the current rebate system is skewing formulary placement, which incentivizes preferred tier placement of drugs with higher-costs and inflated rebates. This is particularly harmful to patients with chronic illnesses like psoriasis and psoriatic disease that increasingly rely on biosimilars to effectively manage their disease. As demonstrated by a recent report “Medicare Part D,”...plans have financial incentive to favor high-priced, higher-rebated reference product than a lower-priced, lower-rebated biosimilar.”²⁰ Following the release of the “Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs” memo in August of 2018, the NPF has monitored MA shifts in coverage and was pleased to see increased access to biosimilars by at least one carrier. In October, United Health Care announced 2019 step therapy requirements for MA plans in a provider bulletin.²¹ This bulletin showed that while new start beneficiaries seeking coverage for Remicade—a drug commonly used to treat psoriasis—would be subject to step therapy, both biosimilars of that originator product – Inflectra and Renflexis – were listed as preferred drugs and did not require step therapy. While this is encouraging, we are seeking further data on the difference in co-insurance for these three products, particularly given recent macro level data showing that in Part D, the differences in co-insurance percentages between a biosimilar and originator product is marginal. For example, a 2017 study which analyzed Part D data showed a difference of only 1.8% between the coinsurance for Inflectra and Remicade²², which minimizes the costs savings to the patient. As HHS considers implementing the portion of the proposed rebate rule and the impact of access to biosimilars, we encourage the agency to pursue strategies that incentivize carriers to lower these out-of-pocket beneficiary costs.

Fixed Fees

We are encouraged by the steps the Administration has outlined within the proposal to require fixed fee service agreements between drug manufacturers and PBMs rather than arrangements tied to percentage of sales or product price. As the department when issuing the proposed rule, “[the fixed fee] proposal would also provide a historic new level of transparency to a system that has been shrouded in secrecy for decades.”²³ We agree with this assessment and believe the fixed fee proposal will offer transparency between drug manufacturers and PBMs, increase the placement of less expensive drugs on the preferred tier of formularies and ultimately reduce out-of-pocket costs for patients with psoriasis and psoriatic disease. As such, we strongly encourage the Administration to maintain this proposal in the finalized rule.

¹⁸ [https://www.jaad.org/article/S0190-9622\(18\)33002-0/fulltext](https://www.jaad.org/article/S0190-9622(18)33002-0/fulltext)

¹⁹ Rule Page 2344

²⁰ <http://www.milliman.com/uploadedFiles/insight/2018/biosimilars-united-states.pdf>

²¹ <https://www.uhcprovider.com/content/dam/provider/docs/public/resources/news/2018/network-bulletin/October-Interactive-Network-Bulletin-2018.pdf>

²² <https://www.healio.com/rheumatology/rheumatoid-arthritis/news/online/%7Bdcf3f185-04df-4a70-86b4-2b2d4fd2aee5%7D/infliximab-biosimilar-only-moderately-less-costly-vs-biologic-under-medicare-part-d>

²³ <https://www.hhs.gov/about/news/2019/01/31/trump-administration-proposes-to-lower-drug-costs-by-targeting-backdoor-rebates-and-encouraging-direct-discounts-to-patients.html>

Medicaid & Private Insurance

While we are supportive of the proposal's intended goal of reducing drug and out-of-pocket costs for Medicare beneficiaries, including those with chronic conditions such as psoriasis and psoriatic arthritis, we remain concerned about the proposal's potential detrimental impact on some state Medicaid programs. Specifically, the CMS OAC found that the elimination of the safe harbor for drug rebates may lead to higher spending by Medicaid managed care organizations (MCOs) and overall increased Medicaid spending of \$1.5 billion over a decade. As a result, the OAC indicated that MCOs would "raise their rates to reflect their own lost rebate revenue."²⁴ Additionally, the office reported that Medicaid is expected to reduce rebate collections by more than the savings from lower prices, which results in an overall increase in cost to the program.²⁵ We are particularly concerned about the impact of this proposal on Medicaid recipients who suffer from chronic illnesses like psoriatic disease, whom we expect may incur higher out-of-pocket costs, reduced quality of care and diminished health outcomes.

We caution the Administration to consider proposal and the impact across insurance markets.

Timeline

As you know, HHS is soliciting comments on the timeline for enactment of the final rule which could be as early as January 1, 2020. We understand that this proposal will require a significant amount of time and capital to implement. However, if the majority of stakeholders within the supply chain are able to ensure timely access to information and the tools beneficiaries will need to shop for health care plans that fit their needs to manage their condition, then we believe the proposed timeline is appropriate.

We appreciate your attention to the comments made by NPF on behalf of the millions of Americans who live with psoriatic disease. Should you wish to reach us to discuss any of our suggestions please contact Matthew Moran, Federal Government Relations & Health Policy Manager at mmoran@psoriasis.org.

Sincerely,



Patrick Stone
Vice President, Government Relations & Advocacy

²⁴ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf>

²⁵ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf>