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April 8, 2019

VIA ELECTRONIC SUBMISSION THROUGH [www.regulations.gov](http://www.regulations.gov)

The Honorable Alex Azar  
Secretary  
Department of Health and Human Services 200 Independence Ave. SW  
Room 600E  
Washington, DC 20201

**RE: Removal of Safe Harbor Protection for Rebates Involving Prescription  
Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale  
Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit  
Manager Service Fees**

Dear Secretary Azar:

The National Osteoporosis Foundation (NOF) is pleased to submit its comments to the above referenced Proposed Rule promulgated by the Department of Health and Human Services (HHS) to remove Anti-Kickback Statute (AKS) safe harbor protection for manufacturer prescription drug rebates in connection with Medicare and Medicaid managed care organizations (MCOs), and include within the safe harbor point-of-sale price reductions and pharmacy benefit manager (PBM) service fees.

The NOF is the nation's leading resource for patients, health care professionals and organizations seeking up-to-date, medically sound information and program materials on the causes, prevention and treatment of osteoporosis. Established in 1984 as America's only voluntary, nonprofit health organization dedicated to reducing the widespread prevalence of osteoporosis, the foundation has grown to include a network of diverse stakeholders that support its goals to increase public awareness and knowledge, educate physicians and health care professionals, and support research activities concerning osteoporosis and bone health related areas.

Our Policy Institute brings together the expertise, resources, and perspective of the full spectrum of bone health stakeholders to advocate for health policy initiatives that promote bone health and reduce both the personal and financial costs of fragility fractures. While the breadth of our mission extends beyond the bone health concerns associated with advancing age, we focus our

comments toward protecting Medicare beneficiary access to osteoporosis treatment options and aligning CMS payment policies with our shared goal of reducing the incidence of and improving the care for fragility fractures in the Medicare population.

## **Background**

In April of 2014, NOF released an update to its prevalence data, revealing that an estimated 10.2 million adults in the U.S. have osteoporosis, and another 43.4 million have low bone mass. This means 54 million U.S. adults, representing 50 percent of the U.S. population over age 50, are at risk of a fragility fracture. Annual fractures are projected to increase from 1.9 million to 3.2 million (68%), from 2018 to 2040, with related costs rising from \$57 billion to over \$95 billion<sup>1</sup>. Our healthcare system is armed with the tools to detect and diagnosis low bone mass and osteoporosis, and an understanding of the risk factors signaling the need for testing. Individuals in whom osteoporosis is detected have a variety of therapeutic options to effectively address their condition and reduce their risk of a fragility fracture.

Despite our ability to identify and manage osteoporosis, Medicare patients continue to suffer fragility fractures at an alarming rate. For the Medicare program, the annual cost of treating these fractures exceeds \$20 billion. Although patients treated for a fragility fracture are at a high risk of future fractures, a significant majority of US hip fracture patients are released from the inpatient setting without any evaluation for osteoporosis and the vast majority are never treated. While we expect the quality of our healthcare to improve with introduction of new diagnostic and treatment options, the care gap in osteoporosis has actually worsened over time.

We reiterate our support for the Administration's efforts to curb the rising cost of prescription drugs and, most importantly, reduce patient out-of-pocket expenses for medically necessary treatments. We agree that the opacity inherent in the current role rebates play in PBM decisions on formulary inclusion and cost-sharing could tend to favor high-cost products with high rebates that are not factored into cost-sharing calculations. Our comments to the Proposed Rule reflect our commitment to ensuring that patients have affordable access to the treatments they need for treating osteoporosis.

***The NOF agrees with the over-arching goal of the Proposed Rule – increasing transparency and ensuring that cost savings negotiated by plans and PBMs are reflected in patient cost-sharing.***

The discount safe harbor was created before both the Part D benefit and the Medicaid MCO regulatory framework were implemented. The NOF shares HHS' concern that the role of rebates to PBMs has evolved to look more like the incentives the AKS was designed to remove than the discounts the safe harbor sought to protect. Rebates play an integral role in drug-formulary decisions, including determining tier placement and even formulary inclusion – they may even be the deciding factor in the medications a patient can receive and how much they pay for them. Unfortunately, if the terms and amount of the rebates are (a) shielded from scrutiny; (b) not

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<sup>1</sup> Lewiecki E. et al. "Healthcare Policy Changes in Osteoporosis Can Improve Outcomes and Reduce Costs in the US." The Journal of Bone and Mineral Research. 15 March 2019.

disclosed to the plan; and (c) not fully captured as savings to patients through either lower premiums or reduced cost-sharing, their connection to the public policy rationales underpinning the discount safe are remote at best.

The NOF shares HHS' interest in exploring and addressing the role of rebates in incentivizing higher list prices and their impact on patient out-of-pocket costs. We continue to believe that a system that encourages manufacturers to lower their list prices and/or provide rebates at the point of sale could provide meaningful savings for beneficiaries, and improve access, affordability, and medication adherence. While we commend the Administration's efforts to lower list prices and improve transparency, we are concerned that the breadth of changes to distribution channel arrangements contemplated under the Proposed Rule, together with its short implementation timeline, could trigger PBM and plan behavior changes with unintended consequences for patients with bone fragility who could benefit from treatment. We urge HHS to consider implementing appropriate guardrails to ensure patients retain affordable access to Part D coverage and the medications they need, and that they are well-informed (and not misled or confused) on the pharmacy benefits provided in each plan, as well as out-of-pocket costs, when determining which plan best meets their needs.

***The NOF encourages HHS to consider the cumulative impact of the Administration's various initiatives to reduce the cost of prescription drugs and limited time for implementing the policies contained in the Proposed Rule.***

The NOF appreciates that HHS outlined its strategy for reducing the cost of prescription drugs in the drug-pricing blueprint released in May 2018 (the Blueprint). The Blueprint laid out a set of initiatives, many of which have been pursued through subsequent rulemaking, that have significant incremental implications for drug pricing, formulary access, and plan flexibility to implement utilization management tools. Each proposal, if finalized, will have a separate impact on drug pricing and patient access across Medicare Part B, Part D, and Medicare Advantage. It is, unfortunately, difficult to ascertain how these policy changes would work together or to anticipate the "final" landscape that this Proposed Rule will be further refining. For example, the Centers for Medicare & Medicaid Services (CMS) has proposed increased flexibility for Part D and Medicare Advantage (MA) plans to leverage utilization management tools so that PBMs can secure the level of discounts and rebates achieved in commercial plans. This Proposed Rule renders some of those arrangements illegal under the AKS.

The NOF is uncertain of whether the cumulative impact of these proposals would maintain, enhance or unduly impede patient access and affordability. We are concerned that PBMs may seek to leverage increased flexibility to implement utilization management strategies as an income stream to replace lost rebate revenue. We are similarly concerned that many of the high-cost treatments with relatively generous rebates could be removed from formulary, placed on a higher tier, or subject to prior authorization and/or step therapy protocols. This would significantly undercut the underlying goal of the Proposed Rule as patients with osteoporosis and other chronic conditions may actually face higher out-of-pocket costs, fewer plan choices, and higher premiums.

The NOF is also concerned that the proposed timeframe for implementing this proposal will make it difficult for manufacturers, PBMs, pharmacies, and plans to devise the system-wide efficiencies and contractual arrangements necessary to ensure that patients benefit and drug costs are reduced. In particular, the ability to apply rebates to the point-of-sale contemplated in the Proposed Rule hinges on development of an efficient, compliant chargeback system. We urge HHS to ensure that plans and PBMs have sufficient guidance and time to implement the necessary contractual changes and chargeback mechanisms. Alternatively, HHS might consider a phase-in that starts with conditioning rebate safe harbor protections on PBMs maintaining rebate transparency and passing on savings to plans and patients.

## **Conclusion**

The NOF appreciates the opportunity to provide feedback as HHS considers implementing the policies outlined in the Proposed Rule. We look forward to working with the Administration toward our shared goal of ensuring that Medicare beneficiaries have access to high-quality care, including medications to treat osteoporosis, to drive improved patient outcomes at a lower cost to the Medicare program.

If you have any questions or wish to discuss our concerns in greater detail, please contact me at 703-647-3020 or our Chief Mission Officer, Claire Gill, at 703-647-3025.

Very truly yours,



Elizabeth Thompson  
Chief Executive Officer  
National Osteoporosis Foundation