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April 8, 2019

Secretary Alex M. Azar II
% Aaron Zajic
Office of the Inspector General
Department of Health and Human Services
Attention OIG-0936-P, Room 5527, Cohen Building
330 Independence Ave. SW
Washington, DC 20201

Re: 42 CFR Part 1001, Fraud and Abuse; 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

Comments submitted electronically at www.regulations.gov

Dear Secretary Azar,

Thank you for the opportunity to submit comments on the proposed rule (file code OIF-0936-P), *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*.

The Global Healthy Living Foundation (GHLF) is a 20-year-old 501(c)(3) patient organization reaching millions of chronically ill patients and their caregivers across the country through social media, community events and our online support and education. GHLF works to improve the quality of life for patients living with chronic disease by making sure their voices are heard and advocating for improved access to care at the community level. Our patients suffer from chronic conditions including arthritis, psoriasis, gastrointestinal disease, cardiovascular disease and migraine. As a result, these patients incur significant financial burden due to the high cost of the treatments that are necessary to manage their disease. And, it is on behalf of the patients we represent that we provide this information for your consideration.

GHLF firmly believes that the success of any efforts to reduce drug prices should be measured by the reduction of financial burden on the patients and the ability of patients to access the treatment deemed best for them in consultation with their health provider. For that reason, we support the intention of the proposed rule “to eliminate rebates from manufacturers to pharmacy benefit managers (PBMs), and replace them with discounts provided to beneficiaries at the point

of sale.” The opaque negotiations and arrangements between pharmacy benefit managers (PBMs) and manufacturers creates perverse incentives to keep list prices high. As a result, both the pharmaceutical and insurance industries financially benefit while patients encounter coinsurance and other out-of-pocket expenses often making therapies inaccessible to them. We often hear stories from our patients about walking away from the prescription counter unable to pay for their medications, rationing or skipping doses to make one prescription last longer, etc. For a patient with a chronic disease like arthritis or Crohn’s disease, consistent adherence to treatment is necessary to keep their symptoms under control and prevent flare-ups that not only lead to their disability and reduced quality of life, but have the potential to unnecessarily burden the healthcare system overall leading to greater expenditures.

GHLF has submitted public comments to numerous dockets focused on reducing drug costs that call for increased transparency on price negotiations and coverage policies, banning utilization management techniques, and increasing or enabling earlier access to generics and biosimilars. Additionally, we have signed on to other comment letters on this docket and we previously commented on rebate policy to the Administration via the proposed Medicare rule *Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P)*. In those comments, we expressed support for a 100 percent mandatory rebate pass-through policy to patients up to the amount of their total out-of-pocket costs each year. It is not fair for a person with a chronic disease to bear the burden of high costs, effectively reducing costs for healthy people. If rebates continue to be allowed under safe harbor, then we would continue to advocate for this pass-through policy. To guarantee its effectiveness, there should be a requirement for a definitional agreement for certain terms that are frequently used by PBMs. We believe strict definitions and mandatory transparency requirements are needed to stop entities from gaming the system by reclassifying money and avoiding pass-through obligations.

In the end, our goal is for beneficiaries to experience reduced healthcare costs and we believe that a total ban on rebates as proposed in the rule would be a sufficient and effective alternative to a 100 percent mandatory pass-through. For this reason, we offer our support for the ban on rebates. We agree with the proposed rule’s assessment that rebates result in inflated list prices as well as PBMs encouraging use of drugs with higher list prices via formulary design and other tactics that discourage the use of lower-cost brand drugs, generics, or biosimilars. The rebates essentially allow manufacturers to buy formulary placement. This epitomizes the definition of a kickback that Congress has legislated against in other industries and we support the Agency’s efforts to redefine the safe harbor in the rule to prohibit this activity.

Through often proprietary and non-disclosed arrangements, PBMs offset their acquisition costs for drugs with high list prices via rebates provided by the manufacturer. However, this rebate is not used to offset beneficiary costs, especially as patients are directed to high priced drugs due to the design of the formulary. In fact, the patient’s coinsurance isn’t a percentage of the net price paid by the PBM, but rather a percentage of the list price. Often, patients are paying more out-of-



pocket for the prescription than their insurance plans, which will only continue to increase as manufacturers inflate list prices to recoup losses from the rebates and other discounts.

If HHS opts to instead allow manufacturers to pay PBMs a fixed flat fee that is not dependent on sales volume or other business generated for services such as medical education and data monitoring, then transparency of these deals is crucial to achieve the cost reductions. While the first condition required by the proposed rule would be for the PBM and manufacturer to have a written agreement of the terms and the services provided, we request that the final rule clearly define what services are allowed in exchange for these fees and which ones are prohibited. Additionally, the terms of these fee arrangements and the written agreements themselves must be publicly available on both the manufacturer's and the PBM's websites. The Centers for Medicare and Medicaid Services (CMS) should require this information to be reported to the agency and then compiled and displayed on the agency's website devoted to information on Part D. Transparency is an effective tool to regulating financial negotiations between manufacturers and PBMs and we encourage the agency to actively take steps to enable this if it were to allow any compensation through a safe harbor.

GHLF understands that the effectiveness of this policy in the proposed rule is contingent on manufacturers reducing their list prices. In theory, without having to pay high rebates to PBMs, they can still maintain current profit levels while reducing the list price. Given that copays and coinsurance are calculated based on the list price, this has the potential to have the greatest benefit to patients in reducing their out-of-pocket costs. This relies on good-natured tendencies and we are concerned that without a mandatory requirement or incentive, manufacturers will not take this action. At a recent Senate Finance Committee hearing, pharmaceutical CEOs indicated that they would only lower list prices to match the net price if rebates were also banned in the commercial market. While saying they would be willing to share some of the rebates with patients at the point of sale, only one CEO out of seven (Pfizer CEO Albert Bourla) said his company would share all of the savings with patients. We recognize that through rulemaking, HHS only has the authority to implement this ban in Medicare, but it would be helpful for the rule to acknowledge the importance of this policy in the private insurance market and the need for legislation to further eliminate these disincentives. Another option would be that in exchange for the ability to engage in the proposed safe harbor for flat fee arrangements with PBMs, HHS could require that manufacturers reveal the net price resulting from arrangements in 2019 and then reduce the list price of a drug to that amount.

The rule acknowledges that eliminating rebates may result in slightly higher premiums. However, the current system is one in which our sickest subsidize our healthy. The chronically ill are twice penalized in life: first with a lifelong medical condition and again through our healthcare system that forces them to pay more for needed therapies rather than spreading those costs throughout society. This rule will bring more economic fairness to our health system.



While higher premiums are undesirable, in the end, the actual savings chronically ill patients would see from the reduction in out-of-pocket costs for their prescriptions would result in overall lower, more transparent costs for them. We request that HHS evaluate and report to the public on the impact on premiums during the first two years after this new policy is implemented. If premium increases are significantly beyond what was anticipated by the actuarial analyses and/or is not offset by the cost savings to beneficiaries, reduced drug costs, etc., then additional actions should be considered to minimize this unintended consequence.

Another unintended consequence of eliminating rebates is access. Today access, especially for autoimmune drugs, is determined largely by rebates. Theoretically, without rebates, price would determine access. In the autoimmune arthritis healthcare segment, there are multiple drugs which allow patients who have failed on one to try others. Downward pressure on pricing to achieve access could cause manufacturers with small market share to withdraw drugs which could work for a specific patient. We need to ensure that this downward pressure does not disadvantage patients who need low-market-share drugs, and that patients realize out-of-pocket cost reductions, or elimination, commensurate with the net lower prices.

Last, the proposed rule suggested an effective date of January 1, 2020. GHLF acknowledges that negotiations for the next plan year are already underway and that it will be extremely challenging for payers and PBMs to adjust formularies, engage in the flat fee arrangements, etc. within the time remaining during this calendar year. Hence, we recommend that the implementation date be extended, using disruption in patient access to medications as the sole criteria.

Thank you very much for the opportunity to comment on this proposed rule and again, for the Agency's efforts to reduce drug prices. Patients with chronic disease face some of the highest out-of-pocket costs for prescription drugs and this is a high priority area of policy for GHLF. We look forward to being a resource to the agency and partnering with policymakers to implement policies that result in patients having greater access to treatment while lowering their costs and costs to the healthcare system. Please do not hesitate to contact me at snewmark@ghlf.org if the Global Healthy Living Foundation, its arthritis community, CreakyJoints, or our arthritis patient registry, ArthritisPower, can be of further assistance with this proposed rule

Sincerely,



Steven Newmark
Director of Policy and General Counsel
Global Healthy Living Foundation

