SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

8 April 2019

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Daniel R. Levinson
Department of Health and Human Services
Office of Inspector General Attention: OIG-0936-P
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201

RE: RIN 0936-AA08; OIG-0936-P ("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")

Dear Mr. Levinson,

The Alliance for Safe Biologic Medicines (ASBM) appreciates the opportunity to comment on the proposed rule that would eliminate the "safe harbor" protection for rebates from pharmaceutical manuafacturers to pharmaceutical benefit manufacturers (PMBs) and insurers with respect to Medicare and Medicaid programs.

ASBM is an organization composed of diverse healthcare groups, including patients, physicians, pharmacists, medical innovators, biosimilar manufacturers, researchers, and others who are working together to ensure patient safety is at the forefront of biologic and biosimilar policies.

ASBM believes that biosimilars are critical to expanding access to biologic therapies for patients with serious conditions including rheumatoid arthritis, psoriasis, Crohn's Disease, and cancer. Given the high cost of biologic therapies, biosimilars are also a valuable tool for controlling healthcare costs for patients and for the larger healthcare system.

Yet the current PBM rebate system represents a commercial barrier which tends to increase rather than lower prices, thus negating the potential cost savings that biosimilars bring to the biologic world. In order for competition to bring prices down, the formulary needs to be based on lowest list price not highest price concession. Consequently, the rebate system actually encourages higher prices and impedes rather than expands access to lower priced biosimilars. It is ASBM's view that the proposed rule will begin to productively address these concerns.

For example, PBMs generally give preferred formulary placement not to the product with the lowest list price, or which provides lowest cost to the patients, but to the product that will provide the PBM the greatest rebate (typically calculated as a percentage of list price). Ironically, because of its lower price, a biosimilar may not be able to win preferred placement on formulary. Ultimately, this has the effect of causing prices broadly to rise, not fall, as manufacturers compete for preferred formulary placement. Rebates are also dependent upon market share. Those medications with the largest market share also have an advantage. This is another aspect of the rebate system that works against penetrance of cost saving biosimilars into the marketplace.

Price concessions to the PBMs also include fees that are often based on a percentage of list price. Thus creating safe harbor for flat market based fees will also reduce the incentive to place higher priced drugs on the formularies.

The proposed rule would permit, but not require, manufacturers to instead offer point-of-sale rebates directly to the patient with "safe harbor" protection. Additionally, this rule offers safe harbor to market

based fees not tied to list price. ASBM supports these provisions as they will increase price transparency, promote competition and most importantly make drugs more affordable for seniors.

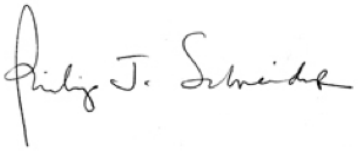
Finally, we urge HHS to be create guidance to ensure that PBMs do not try to circumvent the proposed rule with new utilization management techniques, such as creating overly-restrictive formularies that unfairly limit product choices to one product per class, which could force stable patients to be switched to the preferred product, or by raising out-of-pocket costs so onerously, so as to deny treatment to chronically-ill patients, or to effectively exclude them altogether.

In summary, ASBM supports the proposed rule and believes that it serves the best interest of patients by expanding access to biosimilars, promoting price transparency and competition, and ensuring that control over treatment decisions lay with the patient and his or her healthcare team, rather than with a third party such as a PMB or insurer.

Thank you for the opportunity to comment.

Sincerely,

Madelaine Feldman, MD, FACR
Chair, Alliance for Safe Biologic Medicines



Philip Schneider, MS, FASHP, FFIP
Advisory Board Chair, Alliance for Safe Biologic Medicines

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