February 15, 2022

Re: OIG–1121–N ("Solicitation of New Safe Harbors and Special Fraud Alerts")

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The undersigned organizations represent autoimmune and/or chronic illness patients and the providers who treat them. We thank the Office of the Inspector General (OIG) for its willingness to solicit and consider stakeholder feedback related to existing safe harbors and ideas for potential new provisions. In past years, several of us have engaged in constructive discussions with OIG staff about a safe harbor related to patient cost-sharing assistance and we hope to advance that concept for the reasons outlined herein.

In September 2014, the OIG issued a special advisory bulletin entitled "Pharmaceutical Manufacturer Copayment Coupons," which provided that such coupons constitute "remuneration" offered to customers to induce the purchase of specific items (in this case, certain medications). More specifically, when an item in question is one for which payment may be made "under a Federal health care program (including Medicare Part D)," either in part or in whole, the anti-kickback statute is implicated: "When remuneration is paid purposely to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated." Per the bulletin, copayment assistance programs "may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available[.]"

The OIG has been consistent in its position that drug company copay coupons for brand drugs used in federal health programs constitute a violation of the anti-kickback statute in situations where less expensive and equally effective alternatives exist, which is a position with which we agree. **However, the 2014 bulletin did not directly address whether a coupon is an inducement in situations where less expensive and equally effective alternatives do *not* exist – in other words, in cases where the brand drug is the *only available treatment*.**

In such cases, the potential for inducement does not exist, therefore, the sound policy rationale underlying the prohibition of these coupons for brands with generic alternatives cannot apply. However, since a regulated industry attempting to stay within legal and regulatory bounds will usually answer open questions with the widest possible interpretation of statute and guidance, the result is that pharmaceutical companies currently will not offer any cost-sharing assistance to Medicare and Medicaid beneficiaries for any medication. In situations where no lower-cost alternative exists, this lack of copay assistance does not result in a patient taking the generic versus the brand. **Rather, it can result in a patient not being treated at all to manage their condition(s).** Not surprisingly, a significant body of research has established an inverse relationship between out-of-pocket costs and medication adherence.[1]

This oversight means that some of our nation's most vulnerable patients currently cannot access copayment assistance for expensive medications, which are often their only hope for effectively maintaining their health and avoiding more expensive medical bills when their unmanaged disease inevitably flares. Instead, these beneficiaries are forced to use systemic steroids and/or immunomodulators that increase the risk of long-term adverse health outcomes requiring costlier and highly invasive treatments, like bowel resection and partial or total joint replacement. Worse still, because biologic drug patients have no other effective treatment options, these beneficiaries may go without any treatment at all if they cannot afford their medications.

In light of this patient access barrier, we respectfully request that the OIG issue new guidance indicating that manufacturer copay assistance to federal health program beneficiaries is a violation of the anti-kickback statute *when there is a "less expensive and equally effective generic or interchangeable biosimilar available."* Such a policy would be clear and easy to administer: copay assistance would remain a kickback if provided for any drug that serves as the reference product for an approved and marketed generic or for any biologic that serves as the reference product for a marketed biosimilar that FDA has confirmed to be an interchangeable product. We believe it is important to specify that only a biosimilar deemed by FDA to be interchangeable can approximate an "alternative" to its reference biologic, because only those biosimilars meet the higher statutory threshold requiring evidence that switching will cause no safety issues or loss of efficacy.

In closing, we reiterate our understanding and support for the intent of the federal anti-kickback statute, as well as OIG's longstanding position that drug company copayment assistance constitutes a kickback if it has the effect of driving brand adherence. However, in situations where a less expensive and equally effective alternative does not exist, the potential for inducement is moot because the brand is the only available option. For those situations, we urge the OIG to consider creating a narrow safe harbor as outlined above.

We hope this feedback has been helpful. If you have any questions or if we can provide any additional information, please do not hesitate to contact any of the undersigned organizations.

Sincerely,

American College of Rheumatology
Caregiver Action Network
Coalition of State Rheumatology Organizations
Digestive Health Physicians Association
GBS|CIDP Foundation International
Global Healthy Living Foundation
Good Days
Infusion Access Foundation
Infusion Providers Alliance
Large Urology Group Practice Association
Lupus and Allied Diseases Association, Inc.
National Infusion Center Association
National Organization of Rheumatology Management
Tennessee Hemophilia & Bleeding Disorders Foundation
Texas Rare Alliance
United for Charitable Assistance
US Hereditary Angioedema Association
wAIHA Warriors

[1] See, *e.g.*, Heidari P, Cross W, Crawford K. *Do out-of-pocket costs affect medication adherence in adults with rheumatoid arthritis?* A systematic review. Semin Arthritis Rheum. 2018 Aug;48(1):12-21. doi: 10.1016/j.semarthrit.2017.12.010. Epub 2018 Jan 8. PMID: 29496225.