NATIONAL INFUSION CENTER ASSOCIATION

February 1, 2017

Gregory E. Demske
Chief Counsel to the Inspector General
U.S. Department of Health and Human Services
Office of Inspector General
Room 5527, Cohen Building
330 Independence Ave. SW
Washington, DC 20201

Subject: Anti-kickback statute language restricting patient access to care

Dear Mr. Demske,

I am writing you on behalf of the National Infusion Center Association (NICA) and beneficiaries of federal health care programs unable to receive the care they need because they cannot afford treatment and cannot access manufacturer cost-share assistance programs. Throughout this letter, I will be citing the Office of Inspector General's (OIG) "Pharmaceutical Manufacturer Copayment Coupons" special advisory bulletin from September 2014. The purpose of this correspondence is to express our specific concerns and respectfully request that the OIG issue new guidance on whether pharmaceutical manufacturer cost-share assistance programs, including copayment coupons – for medications paid for by a federal health care program – constitute a violation of the federal anti-kickback statute when there is no "less expensive and equally effective generic or other alternative."

NICA is a nonprofit advocacy organization, established in 2010, that provides a national voice to patients relying on office-based Infusion Centers for the high-quality, cost-effective care they need. NICA and its infusion provider partners are committed to providing a safe, accessible and compassionate care setting for patients with autoimmune and chronic diseases.

Patients must have access to a wide range of therapy so they can find the right treatment protocol – the one that *works*. Our philosophy includes patients with government-subsidized health plans. This is particularly important in the case of medications covered under the medical benefit, including intravenous immunoglobulin (IVIG) and biologic therapies for patients with primary immunodeficiency diseases and immune-mediated inflammatory conditions, like rheumatoid arthritis, Crohn's disease, ulcerative colitis, multiple sclerosis, psoriasis and lupus.

The OIG's guidance is unclear on whether manufacturer cost-share assistance for drugs paid for by a federal health care program violates the federal anti-kickback statute when a less expensive and equally effective generic or other alternative is *not* available. The lack of clear guidance for these particular medications is inadvertently restricting access to critical therapies for some of our nation's most vulnerable patients.

Below explains the OIG's guidance on when copay assistance programs violate the federal anti-kickback statute.

Per the OIG's position stated in the bulletin, pharmaceutical manufacturer copayment coupons constitute remuneration offered to customers to induce the purchase of specific items (in this case, medications). 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." The OIG asserts that copayment assistance programs, including coupons, "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," adding that "excessive costs to Federal programs are among the harms that the anti-kickback statute is intended to prevent."

NICA understands the intent of the anti-kickback statute and agrees with the OIG that the statute was intended to prevent the incentivization of brand-name medication consumption when less expensive alternatives exist. The OIG's guidance is clear that pharmaceutical manufacturer copayment coupons for medications paid for by a federal health care program (including Medicare Part D) – for which less expensive and equally effective generics or other alternatives are available – constitutes a violation of the anti-kickback statute.

However, this guidance does not clarify whether pharmaceutical manufacturer cost-share assistance programs for medications paid for by the medical benefit, including Medicare Part B – for which a less expensive and equally effective generic or other alternative is *not* available – would constitute as a remuneration paid purposefully to induce or reward referrals of items or services payable by a federal health care program, and therefore a violation of the federal anti-kickback statute. This lack of clarity has inadvertently and unnecessarily restricted access to care for beneficiaries of government-subsidized health plans.

Anti-kickback statute language is inadvertently restricting patient access to critical therapy.

Health care innovations made possible by new biologic therapies, and new uses for IVIG, have improved the lives of thousands of patients living with chronic diseases and complex immune disorders. These new therapies come with a significant price increase over conventional chemical therapies. As the cost of drugs increases, so too does a patient's share of that cost. Access to these expensive medical benefit drugs is cost-prohibitive for many of the patients that desperately need them. Manufacturers of these medications have created assistance programs to help manage the financial burden of accessing the critical therapies that hundreds of thousands of patients desperately need by helping cover a portion of the patient's cost-share. These programs significantly reduce financial burdens on patients who have already faced overwhelming obstacles, and make these therapy options available for many patients that otherwise cannot afford them.

Conventional chemical therapies are created using a chemical formula, so it is possible to produce generic medications that mirror the safety profile of the brand-name medication by following the brand-name drug's recipe. Biologics, on the other hand, are much larger and much more complex protein-based medications that are made in living cells. Due to the nature of biologics, it is not possible to create a "generic" version of a biologic that exactly mirrors the safety profile of the biologic product.

Biologics are typically prescribed when conventional therapy protocols, including oral immune suppressants and/or immunomodulators, have failed to effectively manage the patient's condition. Therefore, alternatives include decades-old chemical therapy protocols, which, while less expensive, have proven ineffective, or other biologics with the same indication, which *may* be equally effective but not necessarily less expensive.

According to the federal anti-kickback statute and the OIG's guidance, a drug for which a less expensive and equally effective generic or other alternative is *not* available should not be considered "excess costs to a Federal program," nor should it be considered a purposeful inducement or reward for referrals of items or services payable by a federal health care program, when no generics or alternatives exist.

Therefore, NICA strongly believes that pharmaceutical manufacturer assistance programs that cover a patient's cost-share for a drug (in part or in whole) that is paid for by a federal health care program should not be considered a violation of anti-kickback statute when a less expensive and equally effective generic or other alternative for that drug is *not* available.

Conclusion

Some of our nation's most vulnerable patients are being denied access to copayment assistance for some of our most expensive medications – their only hope for effectively maintaining their health. Instead, these beneficiaries must go back to systemic steroids and/or immunomodulators that have proven ineffective at managing their condition, increasing the risk of long-term adverse health outcomes that require much costlier and highly invasive treatments, like bowel resection and partial or total joint replacement.

Again, NICA understands and supports the initial intent of the federal anti-kickback statute. However, we are compelled to bring these unintended effects to the attention of the OIG and offer our expertise in office-based infusion.

We respectfully request that the OIG issues new guidance to clarify whether pharmaceutical manufacturer cost-share assistance programs for biologics, IVIG and other specialty medications paid for by a federal health care program constitute a violation of the federal anti-kickback statute when a "less expensive and equally effective generic or other alternative" is *not* available.

Alternatively, we are willing to collaborate with the OIG in the exploration and development of all-win strategies that would allow these patients access to manufacturer cost-share assistance so they can receive the critical care they need, while preserving the protections under the anti-kickback statute and safeguarding against the realization of excess costs to federal programs.

Sincerely,

BRIAN NYQUIST, MPH | EXECUTIVE DIRECTOR
NATIONAL INFUSION CENTER ASSOCIATION