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Position Paper on the Government Prohibition of Free Manufacturer Copayment/Financial Assistance for Patients with Government Funded Health Plans Needing Biologic or IVIG Therapies

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"…the US government, as a by-product of broad policy, is actively denying free financial assistance for treatment options to our seniors and our military veterans and their families."

Innovations made possible by new biologic therapies and new uses for IVIG (Intravenous Immune Globulin) have improved the lives of thousands of patients living with chronic diseases and complex immune disorders. These new therapies come with a hefty price tag and much of that cost is now being shared with patients in the form of higher copayments. Manufacturers of these medications have created copayment assistance and free drug programs to relieve some of the financial burdens for patients. Unfortunately, the government's current position is that manufacturer financial assistance programs for patients with government insurance plans (e.g. Medicare, Medicaid, and Military and Veterans Benefits) violate the Federal Anti-Kickback Statute. The rationale for the prohibition is that patients with government funded insurance plans who take advantage of this manufacturer assistance might be encouraged to select a more expensive branded medication over a cheaper generic alternative.

Why is that a problem?

The problem with the government's well-intentioned statute is **that it only works when there *IS* a cheaper generic alternative medication available**. Biologic specialty medications and IVIG have no cheaper generic alternative options, leaving many government funded patients backed into a financial corner with limited treatment options.

Background – The Federal Anti-Kickback Statute

The Federal Anti-Kickback Statute was created to protect patients and taxpayers by attempting to prevent a situation where a financial relationship would influence medical decision making. For many patients receiving health coverage via a federally funded program (e.g. Medicare, Medicaid, and Military and Veterans Benefits), this well-intentioned broad policy creates a problem in certain circumstances.

The current position of the Office of Inspector General (OIG) is that any remuneration or copayment assistance including, *"… print coupons, electronic coupons, debit cards, and direct reimbursements…"* violates the anti-kickback statute.

"The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any Federal health care program. Section 1128B(b) of the Social Security Act (the Act).[2] Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated."

-OIG, Special Advisory Bulletin – September 2013

Like so many well-designed regulations, there is some real merit in the government's rationale. Indeed, data supports the claim that copayment coupons often lead patients and physicians to choose a more expensive brand name medication over a cheaper generic alternative. That all works very well in the brand vs. generic world of most medications.

Consider this simple example below:

Example: A patient has two choices of an oral medication. Med A and Med B

Med A *(Brand):* cost to insurance is $500, patient cost ***WITH*** copayment assistance is $30 *(without copayment assistance the patient cost of Med A would be $100)*

Med B *(Generic):* cost to insurance is $300, patient cost ***WITHOUT*** copayment assistance is $60

The risk is that some patients might assume that the more expensive medication (Med A) is superior and more cost-effective since the financial assistance lowers the patient cost to $30. In this example with a true generic alternative, it is possible that Med B is equally effective and would also save the government insurance plan money.

Admittedly, the issue is complicated. Direct financial assistance for some medications may indeed influence a patient's and physician's decision if that assistance reduces the cost of one company's medication over another. Here is how the OIG put it in their September 2014 report on Copayment Coupons:

"The use of coupons by Medicare beneficiaries could impose significant costs on the Part D program because many coupons encourage beneficiaries to choose more expensive brand-name drugs over less expensive alternative drugs."

-HHS, OIG Study on Safeguards for Copayment Coupons, September 2014

What happens when there are no *"less expensive alternative drugs"* or when the medications are not payable under Medicare Part D or other government funded programs?

Biologics and IVIG Treatments Have Different Economics and Considerations

Let's consider high-cost biologic medications and IVIG. The situation for these patients is very different from the situations outlined by the OIG in their study. Many of these patients are diagnosed with lifelong chronic diseases. For patients receiving high-cost biologic or IVIG medications like Remicade, Gamunex, or Tysabri – their choice of medications is not as simple as the Med A/Med B example above. The economics of the system are vastly different as there are no cheaper generic alternatives. In fact, biologic medications

"The economics of biologic and IVIG therapies are not the same as those the Federal anti-kickback statutes were designed to regulate. A patient who cannot afford a biologic or IVIG treatment option simply does not have a "next best" generic alternative to reach for."

and IVIG are generally delivered intravenously or by injection in the physician's office and are mostly reimbursable under the medical benefit (e.g. Medicare Part B, not Medicare Part D).

Biologic Example: A Medicare Patient receiving an every 8 week infusion of Remicade 600mg for a chronic condition known as Crohn's disease.

At the time of this article, the Medicare reimbursement for this medication is approx: $4,590 per treatment or $32,132 per year (7 Treatments) for the medication alone. For a Medicare patient without a secondary insurance or supplemental coverage, the out of pocket cost for the medication (20%) is: $918 per treatment, or about $6,426 per year.

This same patient's financial situation is similar for other medication options:

Medication and Dosage	Cost Annually*	Patient Cost at 20%*
Remicade 800mg - every 4 weeks	$ 32,132	$ 6,426
Cimzia 400mg - every 4 weeks	$ 31,450	$ 6,290
Entyvio 300mg - every 8 weeks	$ 35,756**	$ 7,151**

**Cost based on April 1st, 2015 CMS ASP+6% reimbursement*
***Cost for Entyvio from April 1st, 2015 CMS NOC List*

All of the above medication options are made by manufacturers who offer some kind of significant copayment assistance for patients with privately funded health plans that, if permissible, could also be made available to patients with government funded insurance.

Alternatives treatments to these standard of care medications are not cheaper generic alternatives, the alternatives are much older standby therapies such as IV and oral steroids, Aminosalicylates (5-ASA), etc. These much older standards carry long-term documented adverse health risks.

A patient faced with the out-of-pocket costs associated with a biologic or IVIG therapy is not making a biologic medication decision based on the availability of a lower cost generic alternative (because there is none). Instead, this patient is forced to make a decision between an innovative effective biologic or immune therapy vs. older antiquated standby meds, or worse no treatment at all.

The majority of government payer patients who cannot afford the premiums for the secondary or supplemental coverage they need, will also not be able to afford the $6,000-10,000 annual out of pocket cost for biologic or IVIG medications. The OIG Bulletin actually acknowledges this difficult situation.

"We (HHS, OIG) recognize that copayment support may benefit beneficiaries by encouraging adherence to medication regimens, particularly when copayments are so high as to be unaffordable to many patients."
-OIG, Special Advisory Bulletin – September 2013

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Many Patients who Need Financial Support, are Not Getting Copayment Assistance.

The sad fact is that many patients who may not need the copayment assistance are getting it (those with Commercial Insurance), while some of the most financially desperate patients (with government insurance plans) are not. For example, a commercial insurance patient with Rheumatoid Arthritis receiving treatment with Remicade, Orencia, or Cimzia medications may pay as little as $100 annually under currently available manufacturer copayment assistance programs. However, a patient with a government health plan, Medicare, Medicaid, or Tricare (Tricare is the Military Insurance), is not be eligible for these free programs regardless of their income.

Foundational Support, or the Lack Thereof

Yes, the government does allow manufacturers to contribute to charitable foundations if they want to offer some form of financial assistance. However, these contributions are not allowed to be directed to a specific medication.

"Manufacturers that desire to assist Federal health care program beneficiaries who cannot afford their copayments have the option of donating to independent charities that provide financial support to patients without regard for the particular medication a patient may be using."

-OIG, Special Advisory Bulletin – September 2013

This is a well-intentioned solution that is unfortunately not a one-sized fits all answer. As stated previously, the problem with this situation is that biologics and IVIG medications have different economics. Because the cost of these medications is very high, and the foundations are allowed to distribute the contributions among many disease states, the foundations often run out of funding for these patients. As of the April 2015, the Healthwell Foundation, a reputable copayment financial support charity for Medicare and commercially insured patients, is reporting that 17 of their 37 funds are closed. At least 3 of the funds that are already closed are for indications covered and/or primarily treated by biologics and IVIG, including the IBD (Inflammatory Bowel Disease which fund covers Crohn's Disease) fund that would cover the Remicade patient in the previous biologic cost example.

Many times, foundation funding for a particular disease or medication is unavailable. Other times, foundation funding is inadequate or runs out before a patient can finish a single year of treatment. **Since the manufacturer has little to no expectation that their financial contribution will actually go towards the intended patient or disease group, there is little motivation to throw money into the foundation fund pile.**

Where Does This Leave the Taxpayers?

Does limiting patient access to these manufacturer copayment assistance programs for government payers make good financial sense? Not likely. Untreated chronic conditions such as Crohn's Disease can lead to more frequent hospital admissions, surgeries, and additional long-term care needs for the patient. There is a long list of chronic conditions known as Primary Immune Deficiencies (PID) that are often

with IVIG. These PID patients have weakened immune systems and, left untreated, can contract a long list of infections that may require aggressive treatment, frequent hospitalizations, and leave long term health problems. **The result of limited access to newer biologic medications and IVIG is additional long-term costs related to caring for these patients whose disease process progresses when left unchecked.**

Ironically, Copayment Assistance *IS* Allowed for Government Subsidized Plans under the ACA
Before changes to the Affordable Care Act (ACA) were made, anyone enrolled in the newly created healthcare exchanges under the ACA was in jeopardy of losing or not being qualified for manufacturer copayment assistance programs. Similar to other government subsidized health insurance (e.g. Medicare, Medicaid, and Veterans Benefits), the lower premiums for these ACA health insurance plans are subsidized by the government.

"Health and Human Services Secretary Kathleen Sebelius… held that the prohibition didn't apply to insurance offered through the exchanges. Such insurance isn't a "federal health-care program" subject to the prohibition."

You can read about the HHS decision here:
http://www.wsj.com/articles/SB10001424052702303843104579172090415391168

Not sure about the double standard? Neither are we. Biologic medications and IVIG have been life changing therapies for many patients suffering from chronic diseases. These therapies allow many patients to lead much more normal and productive lives by keeping their diseases and symptoms in check. These treatments reduce disease progression and thereby reduce additional hospital stays, surgeries, and additional care costs.

As of the date of this paper, the US government, as a by-product of broad policy, is actively denying free financial assistance for treatment options to our seniors and our military veterans and their families. .

"patients enrolled in Medicare, Medicare Part D, Medicare Advantage, Medicaid, Tricare, Veterans Affairs (VA), Department of Defense (DoD), other state- or federally-funded programs, or where otherwise prohibited by law are not eligible for this program."
-Orencia (Abatacept) IV Copayment Assistance Program Terms and Conditions

Proposed Solutions
NICA believes that the OIG, HHS, CMS and other governing authorities should develop a plan or release a safe harbor statement for manufacturers that allows patients with government funded health insurance to participate in manufacturer copayment financial assistance programs when there is not a cheaper generic alternative medication option available to the patient. Manufacturers should be given clear guidelines as to how and when they can offer such programs for government funded health plans in order that they can safely maintain compliance with the current Federal Anti-Kickback Statutes.

NICA is sending letters to CMS, the OIG, and members of congress asking that they look into this very important and urgent patient access issue. If you or someone you know is unable to get the intravenous or injectable medications they need due to this copayment assistance access issue, please write and tell us your story. You can also write your congressman, inform them about this issue, and ask that they support allowing manufacturer copayment assistance for patients with government insurance who need medications with no cheaper generic alternatives. You can find your local congressman/congresswoman's contact information by using the following link: http://whoismyrepresentative.com/.

The opinions written in this paper and of NICA are not intended to be the representative opinions of any of the NICA members, manufacturers, foundations, or any other organization or person mentioned in this writing.

Contact NICA by email for questions:

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