CLIENT ALERT

Charitable Donations Not Grounds for False Claims Act Liability, But Government Scrutiny Continues

Jan.25.2018

False Claims Act liability based on a violation of the Anti-Kickback Statute requires evidence linking the alleged kickback to a specific claim for payment, according to the Third Circuit. The Third Circuit's January 19, 2018 opinion in *U.S. ex rel. Greenfield v. Medco Health Solutions, Inc. et al*., No. 17-1152 comes amidst a broad DOJ investigation of pharmaceutical manufacturers' charitable donations to organizations operating patient assistance programs and sheds light on the evidence necessary to prove that a charitable donation that allegedly violates the Anti-Kickback Statute also gives rise to FCA liability.

The Anti-Kickback Statute prohibits knowingly and willfully offering or paying remuneration to any person to induce that person to refer an individual for services that are paid for by a federal health care program. The Anti-Kickback Statute provides that a claim that includes services resulting from a violation of the Anti-Kickback Statute constitutes a false claim for purposes of the FCA.

In *Greenfield*, the relator alleged that Accredo, a Medco affiliated specialty pharmacy, violated the Anti-Kickback Statute by donating to charities to induce them to refer patients to Accredo. The relator claimed that Accredo violated the FCA by falsely certifying compliance with the Anti-Kickback Statute when it submitted claims for reimbursement for services provided to federally insured patients.

The district court entered summary judgment for Accredo, holding that evidence that Accredo submitted claims for 24 federally insured patients during the same time period that it donated to the charities was insufficient to provide the necessary link between the allegedly improper donations and Accredo's claims to the government. The district court explained that to prevail, the relator must demonstrate that a federally insured patient chose Accredo because of Accredo's donations.

Although DOJ had declined to intervene in the case, it filed an *amicus curiae* brief on appeal, arguing that the district court erred in holding that the FCA required proof that a patient actually chose Accredo because of the charities' referrals. DOJ argued that the district court improperly required the relator "to prove a causal connection between the kickbacks and the claims." DOJ further argued that the district court's opinion appeared to require proof that Accredo's federal claims sought reimbursement for medical care that would not have been provided but for the kickback scheme but that this was not required under the FCA. Instead, DOJ argued, the relator need only "show a connection between the alleged kickbacks paid by Accredo to the charities and the claims Accredo submitted for federal beneficiaries."

The Third Circuit affirmed the district court's summary judgment ruling for Accredo. Even so, it agreed with DOJ that neither the FCA nor the Anti-Kickback Statute requires a showing that a kickback directly influenced a patient's decision to use a particular medical provider. The FCA does require, however, evidence that shows a link or connection between the alleged kickback and a submitted claim. The Third Circuit held that to prevail under the FCA, the relator must show, at a minimum, that one federally insured patient for whom a claim was submitted "was exposed to a referral or recommendation of Accredo by [the charities] in violation of the Anti-Kickback Statute."

In other words, the relator needed to "point to at least one claim that covered a patient who was recommended or referred to Accredo by [the charities]." The relator provided no such link. Not only did he fail to demonstrate that any of Accredo's 24 federally insured patients even saw the charities' approved provider list that included Accredo, but he also failed to establish that any of the patients received the charities' communications regarding Accredo.

The Third Circuit's opinion defining the scope of FCA liability based on an alleged Anti-Kickback Statute violation comes in the midst of DOJ scrutiny of pharmaceutical manufacturers' donations to charities as well as recent Department of Health and Human Services Office of Inspector General (HHS-OIG) actions modifying and rescinding advisory opinions related to such charitable contributions.

Several pharmaceutical manufacturers have publicly disclosed that they have received subpoenas from DOJ requesting information related to donations to various charities operating patient assistance programs. In December 2017, DOJ announced that pharmaceutical company United Therapeutics Corp. agreed to pay $210 million to resolve claims that it used a charitable foundation as a conduit to pay kickbacks in the form of co-pays for Medicare patients taking United Therapeutics' hypertension drugs in violation of the FCA. The recently appointed U.S. Attorney for Massachusetts, Andrew Lelling, explained why his office will continue to focus on pharmaceutical manufacturers' charitable donations to patient assistance programs: "We perceive this as a problem. [I]t's essentially a way to distort the pay structure for Medicaid when it comes to these kinds of drugs, and that seems like an issue."[1][i]

HHS-OIG has also shown a keen interest in charitable donations by pharmaceutical manufacturers and recently modified advisory opinions related to the operation of patient assistance programs. In November 2017, just a month before DOJ announced the United Therapeutics settlement, HHS-OIG rescinded an advisory opinion it initially issued to a charity in 2006 and had updated in 2015. In doing so, HHS-OIG cited "the risk that [the charity] served as a conduit for financial assistance from a pharmaceutical manufacturer donor to a patient, and thus increased the risk that the patients who sought assistance from [the charity] would be steered to federally reimbursable drugs that the manufacturer donor sold."[2][ii] As a result of the rescinded advisory opinion, that charity announced it would not provide financial assistance to patients in 2018.[3][iii]

Earlier this month, on January 8, 2018, Patient Services, Inc. (PSI), a charity that operates patient assistance programs, sued HHS and the HHS inspector general in federal court, claiming that a modified advisory opinion HHS-OIG issued in 2017 placed unconstitutional restrictions on PSI's First Amendment right to free speech.[4][iv] The modified advisory opinion required PSI to certify that it would not solicit suggestions from donors regarding the identification or delineation of disease funds and would not establish or modify funds for specific diseases at the request or suggestion of donors with a financial interest in the funds. The modified advisory opinion further required PSI to certify that it would not provide information to donors that would enable a donor to correlate its donations with the number of patients or the medical conditions of patients who use its products or services. PSI's complaint claims that these provisions create an unconstitutional restraint on PSI's right to free speech and that compliance with them would interfere with PSI's charitable mission of providing financial assistance to patients lacking the resources to pay for life-saving treatments.

While charitable contributions to potential referral sources will likely remain a focus of DOJ and HHS-OIG scrutiny, the Third Circuit's *Greenfield* opinion establishes that charitable donations cannot form the basis of FCA liability absent a link between the contribution and a specific claim for payment.

crowell moring

[1] *See* Alison Noon, Mass.' New US Atty Keeps Heat On Pharma Donations, Law360 (Jan. 24, 2018).

[2] OIG Advisory Opinion No. 06-04 (HHS-OIG), 2017 WL 6032989, at *1 (Nov. 28, 2017).

[3] *A Decision on 2018 Financial Assistance*, Caring Voice Coalition (Jan. 4, 2018).

[4] *Patient Services Inc. v. U.S. et al.*, No. 3:18-cv-00016 (E.D. Va. Jan. 8, 2018).

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

Brian Tully McLaughlin
Partner – Washington, D.C.
Phone: +1 202.624.2628
Email: bmclaughlin@crowell.com

Troy A. Barsky
Partner – Washington, D.C.
Phone: +1 202.624.2890
Email: tbarsky@crowell.com

John T. Brennan Jr.
Partner – Washington, D.C.
Phone: +1 202.624.2760
Email: jbrennan@crowell.com

Lauren R. Nunez
Counsel – Washington, D.C.
Phone: +1 202.624.2559
Email: lnunez@crowell.com

Rochelle-Leigh Rosenberg
Counsel – Washington, D.C.
Phone: +1 202.624.2683
Email: rrosenberg@crowell.com