

Third Circuit: False Claims Act Liability Premised on an Anti-Kickback Statute Violation Requires Proof that at Least One Federal Claim Resulted from an Improper Referral or Recommendation

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by Ben Kappelman

Federal scrutiny of charities that assist patients with accessing prescription drugs has increased with rising prescription drug prices. Some prescription drug charities receive funding from medical providers or drug manufacturers, which can raise questions about whether the charities' funders are using the charities to generate improper recommendations or referrals. In December 2017, the U.S. Department of Health and Human Services Office of Inspector General rescinded a 2006 advisory opinion that had assured a patient-assistance charity that its subsidies for individuals' prescription drug purchases would not subject it to federal Anti-Kickback Statute liability. The OIG's rescission could signal shifting federal policy towards increased scrutiny of drug charities funded by drug manufacturers.

Amidst these changes, a new decision from the U.S. Court of Appeals for the Third Circuit is a good reminder that AKS compliance issues do not automatically translate into FCA violations. In *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, --- F.3d ---, 2018 WL 473158, at *1 (3d Cir. Jan. 19, 2018), the court held that an FCA claim premised on an AKS violation must show that a particular patient was exposed to an illegal recommendation or referral and that a claim for payment for care for that patient was submitted to the government. *Medco* concerned Accredo Health Group, Inc., a specialty pharmacy servicing patients with hemophilia. Accredo supported hemophilia charities, two of which allegedly recommended Accredo as a preferred provider through communications to their members. The relator alleged that this amounted to an AKS violation, which gave rise to an FCA claim because Accredo had certified compliance with the AKS when submitting its reimbursement claims to government payors. Accredo successfully argued to the trial court that the relator's claim failed because he could not show any evidence that any beneficiaries of federal programs chose Accredo because of its alleged improper payments to the charities. On appeal, the relator argued that this amounted to a requirement that he show each patient subjectively sought Accredo's care because of Accredo's charitable donations.

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The court in *Medco* set out to identify “what ‘link’ is sufficient to connect an alleged kickback scheme to a subsequent claim for reimbursement: a direct causal link, no link at all, or something in between.” The United States, as amicus curiae in support of neither party, urged the court to hold that no proof of a patient’s subjective intent to utilize Accredo because of the charities’ recommendation was required to establish an FCA violation. The court agreed, holding that proof of an FCA violation required evidence that at least one of Accredo’s claims sought reimbursement for care provided in violation of the AKS, but that a patient’s subjective reason for choosing Accredo need not be proven.

Nevertheless, the referral or recommendation that violated the AKS must be the referral or recommendation that resulted in the false claim. The court held the relator had failed to show that any of Accredo’s 24 federally insured patients were exposed to the recommendation of the hemophilia charities or that they were even members of the charities. The court explained that “[a] kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient.” The court rejected the relator’s request that the court infer the patients were members of the charities based on the relator’s assertion that “[e]ssentially all hemophelics” in the geographic area Accredo served were members of the charities to which Accredo donated. This inference was not enough because it was impossible to rule out the chance that none of the patients was a member and that none was exposed to the charities’ recommendation. Thus, the relator’s evidence failed to “link Accredo’s alleged kickback scheme to any particular claim” and so Accredo did not face FCA liability.

The court pointed out several issues it did not address in its opinion. It expressed no view as to whether Accredo’s relationship with the charities was an AKS violation in the first place. Nor did the court reach the issues of whether the relator could satisfy the FCA’s materiality requirement, even if he had shown a link between the patients exposed to the charities’ recommendation and Accredo’s claims. And although not addressed by the court, the low number of federally insured patients at issue—24—means the court did not have an opportunity to address claims against a provider who services a large number of federally insured patients. *Medco* does not explain what evidence would be sufficient to show at least one of a large number of patients were exposed to an improper referral or recommendation. Still, the *Medco* decision is a useful reminder that the AKS and FCA have separate elements, and an AKS violation does not automatically translate to FCA liability. Organizations in the healthcare space—particularly charities—should take heed.