$43 Million False Claims Act Verdict in Minnesota Illustrates Ongoing Anti-kickback Statute Risks

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On February 27, a Minnesota federal court jury ruled in the favor of the U.S. Department of Justice (DOJ) in a False Claims Act (FCA) case based on allegations of Anti-kickback Statute (AKS) violations. The focus of the case was on "lavish hunting, fishing and golf trips, private plane flights, frequent-flyer miles" and other remuneration allegedly provided to ophthalmologists to induce them to use the defendants' products. The $43 million verdict handed down in *U.S. ex rel. Fesenmaier v. The Cameron-Ehlen Group Inc. et al.* could grow significantly due to the potential for triple damages and per claim fines of between $5,500 and $11,000 under the FCA. While it is unclear how much the total recovery will be, application of the minimum per claim fine along with treble damages points to an amount that could exceed $400 million.

The Anti-kickback Statute & False Claims Act

Like many FCA actions, the *Fesenmaier* case arose from allegations made by a whistleblower who filed a complaint with the DOJ. A key reason the FCA has been so successful as a vehicle for pursuing health care fraud is because of the financial incentive available to individuals who bring these cases to the attention of DOJ which allows those individuals to receive a portion (between 15% and 30%) of the recovery. Whistleblowers in FCA cases were paid over $488 million in fiscal year 2022 from these cases. The whistleblower in *Fesenmaier* worked for the corporate partner of one of the defendants for approximately 15 years and served as a Vice President of that company for a period of time.

In general, the AKS makes it illegal to pay or receive anything of value to induce or reward referrals or the purchase of services and other items reimbursable by federal health care programs like Medicare and Medicaid. Allegations that the AKS has been violated are often prosecuted under the FCA, which prohibits, among other things, knowingly presenting false claims for payment to Medicare and other programs. The FCA provides for per claim penalties (during the time period at issue in *Fesenmaier*) of between $5,500 and $11,000 along with damages in an amount that is three times the government's damages. The per claim amounts available under the FCA are adjusted from time-to-time and most recently have increased to a minimum of $12,537 and a maximum of $25,076.

The Allegations

According to the complaint, the defendants allegedly provided a variety of kickbacks to persuade physicians to buy products, services and equipment made available by defendants and their corporate partner. Activities included:

- Taking physicians on "lavish trips" for free.
- Providing private flights to physicians for free or at heavily discounted rates.
- Providing frequent flier miles to physicians for free or at heavily discounted rates.
- Allowing physicians to take trips for well below fair market value.
- Paying for expensive meals and entertainment.

The DOJ press release notes that the kickbacks took various forms, including "high-end skiing, fishing, golfing, hunting, sporting and entertainment vacations" and such things as trips to the College Football National Championship and the Masters golf tournament. The complaint recites numerous examples of alleged kickbacks, such as dinners at expensive restaurants, wine, ski trips, private flights, helicopter rides and tickets to Vikings, Packers and Twins games. This was done, according to the complaint, in an effort to get physicians to use defendants' products in various ophthalmology procedures; for example, by inducing physicians to convert from interocular lenses (IOLs) that they were currently using in cataract surgery to IOLs made available by the defendants.

According to the DOJ press release, the defendants maintained a secret fund or slush fund in furtherance of the kickback scheme. The defendant Cameron-Ehlen Group, Inc. used money from the secret fund to finance multiple physician trips. The complaint notes that physicians would sometimes be invoiced for a portion of the travel and other expenses. Some physicians were allegedly charged amounts approximating the value of trips, while others were not required to make any payment or paid an amount that was well below the cost of the trips.

Past as Prologue?

Many of the allegations concern conduct that the agency in charge of AKS enforcement, the Office of Inspector General at the U.S. Department of Health and Human Services (OIG), has been warning about for decades. For example, in one of its earliest Special Fraud Alerts, published in 1994, the OIG cautioned against "airline discounts and related travel premiums" given to physicians in exchange for prescribing or providing specific products, along with "'frequent flier' campaign[s] in which physicians were given credit towards airline frequent flier mileage each time the physician completed a questionnaire for a new patient placed on [a] drug company's product". Similarly, in its 2003 Compliance Guidance for Pharmaceutical Manufacturers, the OIG cautioned against: "[e]ntertainment, recreation, travel, meals or other benefits in connection with information or marketing presentations", as well as "gifts, gratuities and other business courtesies" if any one purpose of the arrangement is to generate business for the pharmaceutical

manufacturer.

The jury in *Fesenmaier* found that the kickbacks at issue led to the submission of 64,575 false claims to Medicare between 2006 - 2015. DOJ has indicated that it will seek treble damages under the FCA, which suggests that the $43 million verdict could become approximately $129 million, and in addition will seek statutory penalties for each false claim. In light of the minimum per claim fine of $5,500 and the maximum fine of $11,000 — alongside the 64,575 claims the jury found to be false — the approximate total exposure could be a staggering $484 million (as calculated using the minimum $5,500) and over $839 million if the maximum fine were to be applied.

What Lessons Can be Learned?

In recent years, the fraud and abuse enforcement actions that have tended to grab the public's attention have often focused on hospital — physician arrangements, the use of technology to generate business and interpretations of critical regulatory standards like "fair market value" or whether compensation "takes into account" the volume or value of referrals. The *Fesenmaier* case, however, shows that relators and the DOJ remain focused on arrangements that present more straightforward AKS concerns.

As noted above, early OIG guidance on the AKS is relevant to at least some of the activities alleged to have occurred in *Fesenmaier*. This suggests that the agency's numerous Special Fraud Alerts, Special Advisory Bulletins, Compliance Guidance and related materials continue to offer valuable lessons for providers in spite of the fact that many years have passed since some of them were originally released. It is a natural tendency to focus compliance efforts on new developments and emerging areas of concern, but *Fesenmaier* illustrates the importance of staying on top of older concerns expressed by OIG and other agencies.

Moreover, the complaint alleges that a variety of documents and internal communications demonstrated knowledge of the AKS and its restrictions on entertainment practices involving referral sources. Enforcement agencies tend to take a hard line where there is evidence suggesting that regulated parties are aware of guidance indicating that particular activities are problematic under health care fraud and abuse restrictions yet choose to proceed anyway.

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If you have questions about the AKS, FCA or the *Fesenmaier* case, please contact Jesse Berg (jesse.berg@lathropgpm.com / (612) 632-3374), Eric Yaffe (eric.yaffe@lathropgpm.com / (202) 295-2222) or your Lathrop GPM attorney.