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The Eliminating Kickbacks in Recovery Act in False Claims Act cases: the coming battleground

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In recent years, many cases under the False Claims Act (FCA) — both those filed by whistleblowers and those initiated by the Department of Justice — have been based on health care providers' alleged violations of the Anti-Kickback Statute (AKS). The standard theory is that by paying undisclosed kickbacks to obtain patient referrals and then billing the government for treating the patients, the providers have submitted explicitly or implicitly false claims.

The Eliminating Kickbacks in Recovery Act (EKRA), enacted in 2018, potentially creates another avenue for FCA cases, extending the ban on kickbacks to cover patients of addiction treatment companies and diagnostic laboratories in some cases where the AKS does not apply.

As the COVID pandemic has greatly increased the demand for lab testing and DOJ has cracked down on laboratory billing abuse, one might expect a surge in EKRA-based FCA cases. The whistleblower bar has identified EKRA as a key area of interest. But so far, it's been crickets on the litigation front. Why?

AKS preemption of EKRA: Not a total eclipse

One possible explanation: the AKS partially preempts EKRA. Under 18 U.S.C. § 220(d)(1), if conduct already violates the AKS, it is not covered by EKRA. Since the AKS covers kickbacks in nearly all federal health care programs, most such kickbacks violate that statute and thus can provide the basis for a FCA case; EKRA is simply not needed.

But that still leaves other cases in which EKRA could apply to kickbacks paid to federally-insured patients. While EKRA's subsection (b) contains various exceptions styled after AKS's safe harbors, they are in some cases narrower, and thus EKRA prohibits conduct (by laboratories and addiction treatment providers) that AKS does not.

For example, while an AKS safe harbor exempts payments to "bona fide employees" for recruiting patients,[1] EKRA does not allow such payments if they are based on the volume or value of "referrals."[2] Thus, a laboratory that pays sales staff on commission for referral of Medicare or HRSA patients could violate EKRA, even if it does not violate the AKS. Could DOJ or a whistleblower make a FCA case in that situation?

Materiality: A key hurdle in EKRA-based FCA cases

Perhaps, but there is another obstacle to such a claims, one that may feature heavily in future EKRA-based FCA litigation: materiality. To win, an FCA plaintiff must prove that the false claims the defendant made were material to the government's decision to pay. In *Universal Health Services v. U.S. ex rel. Escobar*,[3] the Supreme Court gave extra teeth to the materiality requirement, deeming it a "demanding" standard not satisfied by "minor" compliance issues.[4]

As the COVID pandemic has greatly increased the demand for lab testing and DOJ has cracked down on laboratory billing abuse, one might expect a surge in EKRA-based FCA cases.

But in cases based on the AKS, this has generally not been a challenge, ever since a 2010 AKS amendment provided that any claim "resulting from" a kickback is automatically a false claim.[5] Courts have often interpreted this to mean that post-2010 AKS violations are virtually *per se* material to the payment decision.[6]

There is no such provision in EKRA. Thus, EKRA-based FCA claims are subject to the *Escobar* standard for materiality. But how would courts apply that standard to a situation involving kickbacks in violation of EKRA?

For example, how would they decide whether a lab's payment of volume-based commissions to its sales staff for bringing in Medicare patients was material to the government's payment of claims for the lab's services?

Without EKRA-based FCA cases as precedent, we can look for guidance to how courts have approached AKS violations preceding the 2010 amendment. Some courts have said that such violations are not necessarily material, in that it is possible the government may have paid claims despite the involvement of kickbacks.[7] Others have found that such payments were *per se* material, even before the 2010 amendment.[8]

Arguably, though, the case for materiality is weaker for EKRA violations than for AKS violations.

In *Escobar*, the Supreme Court listed four factors relevant to determining materiality:

- Whether the government expressly identifies compliance with a statute or regulation as a condition of payment;
- Whether violations of such statute or regulation go to the "essence of the bargain" between the government and the defendant;
- Whether the government consistently pays or refuses to pay claims when it knows of violations of those conditions; and
- Whether the government paid particular claims in full despite knowing of violations.

Some courts considering AKS-based FCA claims have reasoned that it is "common sense" that AKS violations would be material to government payment decisions, as the AKS is "a felony statute requiring specific intent," goes to the "essence of Medicare's bargain with participating healthcare providers," and has been the subject of numerous settlements and government enforcement actions.[9]

It is hardly intuitive that the government would have sought to deter labs from testing for COVID simply because they had paid employees to bring in patients.

Some of that reasoning applies to EKRA, which is also a felony statute whose violation requires not only intent, but willfulness. But other aspects of those courts' analysis and the *Escobar* factors do not so clearly apply.

Given EKRA's relative novelty, it cannot be said that the government has a long track record of enforcement. This is particularly true of cases involving Medicare or other government funds (such as FCA cases); as discussed above, such cases typically fall under the AKS, and thus the government often need not and cannot invoke EKRA in those situations. To date, government enforcement of EKRA appears to be limited mainly to cases involving private insurance claims.

Nor is it clear that EKRA goes to the "essence" of the bargain between the government (whether Medicare, Medicaid, or HRSA) and providers, or that the government "consistently" takes a position on payment in the context of EKRA violations.

Again, because EKRA was largely aimed at expanding anti-kickback rules to the private-payer context, and only applies when AKS does not, it does not appear to have been a particular focus of government claims payment decisions.

That point is perhaps strongest as to diagnostic laboratories providing services outside of the addiction treatment context. While such services are technically covered by EKRA, the statute's title (particularly the word "Recovery") and legislative history make clear that it was aimed at the addiction treatment industry; its expansion to other forms of lab testing appears to have resulted from a rushed drafting process that one Congressman warned "may have unintended consequences."

There is reason to question whether Congress would have wanted federal program administrators to base payment decisions on whether, for example, laboratories paid their own sales employees on commission for bringing in medically appropriate cases not involving addiction treatment.

The above point has been particularly acute regarding COVID testing during the pandemic. Almost from the beginning, federal policy has essentially been to encourage as much testing as possible.

President Biden touted his administration's expansion of access to testing, including the increase in free testing sites around the country, relaxed restrictions on insurance coverage for testing, and requirements that private insurers cover testing, on the view that increased testing served the public interest as well as individual patients. It is hardly intuitive that the government would have sought to deter labs from testing for COVID simply because they had paid employees to bring in patients.

Further, legislative silence on EKRA's relationship to the FCA may weigh against materiality. As discussed above, while Congress expressly made claims "resulting from" AKS violations automatically "false" under the FCA, it chose not to add a similar provision for claims resulting from EKRA violations. That omission arguably suggests that EKRA violations weigh differently.

Forecast: Excitement aplenty, for the FCA bar

EKRA-based FCA claims are a matter of when, not if. With the encouragement of the relator bar, employees of labs that have not yet adjusted to EKRA's intricacies — perhaps still paying sales employees based on referral volume or relying on another inapplicable AKS safe harbor — will file *qui tam* complaints alleging all related billing is compromised.

Given the continuing disagreement among courts and litigants regarding *Escobar* in general, as well as the dearth of EKRA precedent, this will light interpretive fireworks over statutory language, federal program policy, and the Supreme Court's definition of materiality in a new context. Labs and addiction treatment providers that fail to update their EKRA compliance policies may find they have a front-row seat to the show.

Notes

[1] 42 C.F.R. § 1001.952(i).

[2] 18 U.S.C. § 220(b)(2).

[3] 579 U.S. 176 (2016).

[4] *Id*. at 194.

[5] 42 U.S.C. § 1320a-7b(g).

[6] *See U.S. ex rel. Arnstein v. Teva Pharmaceuticals USA, Inc.*, 2019 WL 1245656, at *28 (S.D.N.Y. Feb. 27, 2019).

[7] *See Arnstein*, 2019 WL 1245656, at *28-29.

[8] *See United States v. Berkeley Heartlab, Inc.*, 2017 WL 6015574, at *2 (D.S.C. Dec. 4, 2017)(citing cases from 1st, 3rd, and 11th circuits).

[9] *See U.S. ex rel Longo v. Wheeling Hospital, Inc.*, 2019 WL 4478843, *8-9 (N.D. W.Va. Sept. 18, 2019); *Thornton v. National Compounding Co.*, 2019 WL 2744623, *23 (M.D. Fla. July 1, 2019).

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