SAFE HARBORS LESS SAFE IN OHIO

In a new case from the Southern District of Ohio, US_v_MillenniumRadiology, the court denied a motion to dismiss a False Claims Act suit, finding that compliance with a safe harbor could only be raised on summary judgment. The court also found that uncompensated service as a medical director could form the basis for a False Claims Act suit based upon violation of the Anti-Kickback Statute.

Millennium Radiology and Mercy Health Partners entered into a series of agreements making Millennium Mercy's exclusive radiology provider. Mercy provided the space and equipment needed to provide the services, Millennium billed professional components and Mercy billed technical components of radiology services. Mercy also paid Millennium a lump sum for start-up costs, a monthly advance for operating costs and, in the first agreement, a salary for medical director services. In a subsequent agreement, Mercy added a recruiting allowance of up to $25,000 per physician to recruit two physicians and dropped compensation for the medical directorship. Relator, a former Millennium employee, alleged Millennium marketed Mercy to other doctors in exchange for an illegal kickback, the agreement with Mercy. He also alleged that Mercy's attorney advised that the agreement might be illegal.

The court agreed with defendants that relator was required to allege that Millennium received something, in this case marketing and medical director services, for less than fair market value. However, the court then concluded, "providing these services for free would necessarily be providing them at below market rates and below costs."

In a footnote, the court refused to consider the defendants' argument they met the "Personal Services Arrangement Safe Harbor" to the AKS, concluding safe harbors are affirmative defenses; therefore, the court reasoned, they were to be considered at the summary judgment rather than the motion to dismiss stage. While this makes sense from a purely procedural point of view, it is contrary to the prevailing law and the purpose of safe harbors.

Safe harbors are regulatory in nature. They assure providers that they can take actions that, while technically in violation of the FCA, are acceptable to the Medicare program. Compliance with a safe harbor, therefore, should be considered at the motion to dismiss stage to show lack of knowledge on the part of the defendant. False Claims Act law is rife with decisions that state reliance upon regulations or direction from the government shows a lack of knowledge sufficient to allege an FCA violation. In *US ex rel. Lee v. Corinthian Colleges*, 655 F.3d 984 (9th Cir. 2011), the court stated the relator was required to plead, at the motion to dismiss stage, that the defendant "knew, or acted with reckless disregard of the fact that [its program] did not fall within the DOE Safe Harbor Provision;" or "even if it believed [it fell under the Safe Harbor Provision], it knew or acted with reckless disregard of the fact that, in reality, [individuals were acting outside that provision]." *Id*. at 997. This is consistent with a long body of case law that holds government contractors relying on good faith interpretations of regulations are not subject to FCA liability. See, e.g. *US ex rel. Oliver v. Parsons Co*., 195 F.3d 457, 464 (9th Cir. 1999). Other District Courts have required relators to allege noncompliance with a safe harbor provision at the motion to dismiss stage. See, e.g., *US ex rel. Carpenter v. Abbott Laboratories, Inc.*, 723 F.Supp.2d 395 (D.Mass. 2010); *US ex rel. Osheroff v. Humana, Inc.*, 2012 WL 3379072 (S.D.Fl. 2012); and *Parikh v. Citizens Medical Center*, 977 F.Supp.2d 654 (S.D.Tx. 2013).

False Claims Act cases are tremendously complex and expensive. The idea that a defendant could rely upon a regulatory safe harbor yet be forced to participate in discovery that can cost millions of dollars is shocking. From a purely procedural standpoint, it might make sense because the defendant would ultimately be given an opportunity to rely upon the safe harbor to defeat the prosecution. However, in reality, reliance upon the safe harbor in the face of FCA expense and potential liability, is so cheapened that it may well become useless. The decision, should it be followed in other courts, would defeat the purpose of the safe harbor.

If you have any questions or would like more information on this topic, please contact David B. Honig at (317) 977-1447 or dhonig@hallrender.com or your regular Hall Render attorney.