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When Gov't Knowledge Of Industry Practice Bars FCA Claims

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On Nov. 16, 2017, the Third Circuit ended a long-fought False Claims Act case of alleged Medicare Part D fraud, holding that a pharmacy benefit manager's (PBM's) limited noncompliance with pharmacy claims processing requirements was not material to Medicare's payment decisions within the meaning of the U.S. Supreme Court's Escobar decision.[1] The Third Circuit's affirmation of the district court's summary judgment dismissal in United States ex rel. Spay v. CVS Caremark Corporation[2] relied heavily on evidence that the government was aware that the alleged noncompliance was an industry practice, even though the government may not have been aware of the specific PBM's alleged noncompliance. For an in-depth discussion of Escobar's materiality requirement, click here.

Interestingly, in Spay, the Third Circuit adopted the government knowledge inference defense, thereby offering FCA defendants in the circuit another weapon in their arsenal of defenses to obtain dismissal of FCA claims. As formulated by the court, the government knowledge inference defense has two prongs: "(1) the government agency knew about the alleged false statement(s), and (2) the defendant knew the government knew."[3] Despite announcing this test, the court determined that the PBM could not satisfy its requirements, holding that although evidence of the government's knowledge of an industry-wide lack of compliance with certain prescription drug claims processing requirements satisfied the first prong, there was no evidence to satisfy the second. Nevertheless, the court ruled that this evidence of the government's knowledge was sufficient to establish that alleged false statements regarding those requirements were not material to the government's payment decision within the meaning of Escobar.

Spay clearly represents a defense victory and acknowledges the existence of a new potential defense in the Third Circuit. However, from a practical standpoint, it is not clear whether the defense is needed in light of its close relationship to the Escobar materiality requirement, which does not require satisfying a two-prong test.

The District Court Decision

In 2007, one year after the Part D program began,[4] relator Anthony Spay conducted an audit for an

insurance client and made certain audit findings regarding the defendant PBM, particularly the PBM's use of "dummy" prescriber IDs in its pharmacy claims processing. Spay, 2017 U.S. App. LEXIS at *7. Two years later in 2009, the relator filed an FCA case in the Eastern District of Pennsylvania, alleging that the Part D insurance plans, known as sponsors, through the defendant PBM, had submitted false information to the Centers for Medicare & Medicaid Services about their prescription drug costs. This information was used in an annual reconciliation process to determine CMS's average payment per beneficiary due to the sponsors. In essence, the relator contended that each Part D claim with a dummy prescriber ID was false because the PBM, as the sponsors' agent, implicitly certified the accuracy of those claims. The government declined to intervene in the case, which was unsealed and pursued by relator on behalf of the United States.[5]

As backdrop, the Third Circuit explained that the Part D program required sponsors to submit prescription drug event (PDE) data comprised of at least 34 mandated data fields; this information typically was submitted by the sponsors' PBMs. The data fields at issue in Spay were the Prescriber ID — which could have been a national provider identifier (NPI), universal provider identification number (UPIN), a state license number, or a U.S. Drug Enforcement Administration (DEA) number — and the prescriber ID qualifier, a field that identified which of the four prescriber IDs was to be submitted.[6] An otherwise valid prescription submitted with a blank prescriber ID or prescriber ID qualifier field would generate an error code, which would prevent the pharmacy from being paid for dispensing the medication.[7] As a workaround, the PBM entered a "dummy" prescriber ID into the data field, which allowed the claim to process and the pharmacy to be paid.[8]

The district court made the following findings based on the undisputed facts, including deposition testimony of individual CMS employees:

- In 2006-2007, CMS knew sponsors and PBMs were having trouble obtaining accurate prescriber IDs;
- CMS "clearly knew of dummy prescriber usage" in the industry;
- At times, CMS "affirmatively instructed Sponsors and PBMs [not including defendant PBM] to submit dummy prescriber IDs when a unique number was not available;"
- CMS did not "issue affirmative instructions mandating the use of a unique identifier" until after 2007; and
- Consistent with a key goal of the Part D program, CMS "prioritized the filling of valid pharmacy claims over the administrative requirement of populating" the prescriber ID field. [9]

At summary judgment, the district court held that the PBM's evidence of the government's knowledge concerning dummy prescriber IDs "preclude[d] finding the required element of scienter" for FCA liability.[10] To reach this conclusion, the district court relied on the government knowledge inference defense, a theory adopted by six other circuits, although not previously addressed by the Third Circuit. In the district court's formulation, the defense was based solely on the government's knowledge and approval "of the facts underlying an allegedly false claim prior to presentment."[11]

Third Circuit Opinion

On appeal, the Third Circuit affirmed the district court's grant of summary judgment, but it did so on the basis that the relator could not satisfy Escobar's materiality requirement, and veered away from the government knowledge inference defense as it had been applied by the district court. In considering this issue of first impression, the Third Circuit expressly adopted the government knowledge inference defense but rejected the district court's formulation of the defense, instead applying a two-prong test that incorporated knowledge requirements for both the government and the defendant. With the Third Circuit's decision in Spay, the defense now is recognized in seven circuits (First, Third, Fourth, Fifth, Sixth, Eighth and D.C. Circuits).

Government Knowledge Inference Defense

The Third Circuit explained that the government knowledge inference defense "focuses on the effect the government's knowledge has on the defendant's mental state in order to determine if the defendant acted knowingly," i.e., with the required scienter for an FCA violation.[12] In the Third Circuit, for the defense to preclude FCA liability, the court held that a two-prong test must be satisfied: the defendant must establish that "(1) the government agency knew about the alleged false statement(s), and (2) the defendant knew the government knew." [13] The Third Circuit explained that, contrary to the district court's formulation, "knowledge by the government, without more, cannot negate the scienter requirement," because scienter focuses on the defendant's mental state with respect to the precise claims at issue.[14] Accordingly, there also must be evidence that the defendant knew that the government was aware of the allegedly false claims.

The Third Circuit's opinion also appears to imply an additional component to the required government knowledge — evidence that the government (explicitly or tacitly) acquiesced in the submission and payment of the alleged false claims at issue.[15] ("While it is true that both the government and contractors throughout the industry knew what was happening, there is no evidence of any explicit approval from the government to [defendant PBM] of this temporary workaround"). Indeed, the Third Circuit stated that the defense "might be more aptly named a 'government acquiescence inference.'"[16] The court explained that a strong example of evidence sufficient to satisfy both of the defense's requirements would be explicit and direct instructions from the government to the defendant concerning submission of the claims at issue; however, the court noted that "such direct and contract-specific authorization is not required."[17]

Applying its newly articulated two-prong test to the record in Spay, the Third Circuit held that while there was "ample evidence of government knowledge of the industry practice at issue, the evidence to satisfy the second prong is lacking."[18] Although available evidence indicated that the PBM knew the use of dummy prescriber IDs was widespread in the industry and that "CMS seemed to allow" this practice, there was no evidence that the PBM knew "that CMS was aware of the practice of using dummy prescriber IDs."[19] The court noted that the PBM's manager in charge of claims submission testified that he was not aware of any discussions between the company and CMS about dummy prescriber IDs or any guidance from CMS on this point. Rather, "the record shows [only] that [the PBM] was simply hopeful that its use of the dummy IDs would be acceptable."[20] For that reason, the Third Circuit ruled that the district court erred when it determined that the defense warranted summary judgment against the relator.

Materiality

Although the PBM's evidence of government knowledge, without more, could not establish the government knowledge inference defense, that same evidence was sufficient for the Third Circuit to find

that use of dummy prescriber IDs was not material to the government's payment decision. This determination was fatal to the relator's claims.

The Third Circuit pointed to the undisputed facts from the district court record that "CMS knew that dummy prescriber IDs were being used by PBMs, that it routinely paid PBMs despite the use of these dummy prescriber IDs, and that CMS only signaled a change in position well after" the years at issue in the relator's FCA suit.[21] The court noted that the relator did "not contest that CMS employees knew that dummy identifiers were being used," [22], although the relator did challenge whether these CMS employees' deposition testimony constituted knowledge by CMS — a position that the Third Circuit rejected without much elaboration, citing the widespread practice of individual agency employee testimony establishing agency knowledge.[23]

Finally, in adopting the district court's view that the relator's "case appears to be nothing more than an effort to convert an unprofitable private audit — performed at a time when Part D regulations were new and not as explicit in their instructions — into a successful recovery of funds under the guise of a qui tam action," the Third Circuit explained the distinction between actionable fraud and necessary workarounds that did not constitute fraud:

> The dummy Prescriber IDs were intended as one thing, and one thing only: they were intended as a technical, formulaic way of preventing a computer program from denying legitimate claims for reimbursement and payment for prescriptions that were actually disbursed to Medicare recipients. Those recipients needed the prescriptions the claims were based on, and nothing here suggests that the prescriptions or the workaround that prevented legitimate claims for payment from being improperly rejected by a computer code served anything other than the practical purpose of facilitating that payment and disbursement of those prescriptions. The workaround could arguably be described as "creative," or a "common sense solution" to a very real and perplexing problem. But we see nothing that would justify calling it "fraud." The claims themselves were neither false nor fraudulent. Nothing in the text or history of the FCA leads us to conclude that Congress intended conduct such as this to morph into actionable fraud against the government.[24]

Takeaways for Government Contractors

The second prong of the government knowledge inference defense involves providing evidence about the defendant's own knowledge, practices and interactions with the government. Establishing a failure of Escobar materiality requires no such showing. The Supreme Court made clear in Escobar that proof that the government knowingly and routinely paid claims with the same defect as the claims at issue is sufficient.[25] ("if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material").

As in Spay, evidence regarding materiality also is sufficient to satisfy the first prong of the government knowledge inference defense test. But if a defendant can either establish the first prong of the government knowledge inference defense to FCA liability or the complete Escobar materiality defense with the same evidence, why use the government knowledge inference defense at all? Likely, it will most often be used in the instances of demonstrable explicit communications between the defendant and the government regarding the noncompliance at issue. Otherwise, Escobar's materiality requirement is the clearest path to dismissal.

As result, companies that contract with the government should take the following steps in response to the decision:

- Get appropriate legal advice about technical or administrative program/contract requirements that cannot be met;

- Be prepared to be evaluated as to how the company's processes compare to others in the industry;

- Do not rely solely on industry-wide noncompliant practices to fend off FCA claims, but consider the benefits of being open with the government (and gaining its acquiescence) about workarounds of requirements that are difficult or not capable of being accomplished; and

- Most importantly, make a record of the communications between the company and the government to defeat potential FCA liability under the government knowledge inference and materiality defenses laid out in

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[1] See Universal Health Servs. Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 1996 (2016).

[2] No. 15-3548, 875 F.3d 746, 2017 U.S. App. LEXIS 23027 (3d Cir. Nov. 16, 2017); hyperlink at http://www2.ca3.uscourts.gov/opinarch/153548p.pdf.

[3] Id. at *16.

[4] The Medicare Part D Program began on Jan. 1, 2006. See 42 U.S.C. § 1395w-101(a)(2). The Part D program provides for prescription drug coverage for Medicare beneficiaries through insurance companies and other private companies approved by Medicare. See https://www.medicare.gov/part-d/index.html (last visited Nov. 28, 2017).

[5] Id. at *7-*8.

[6] Id. at *4-*6.

[7] Id. at *5-*6.

[8] Id. at *6-*7.

[9] Id. at *20-*21 (internal quotation marks omitted).

[10] Id. at *8.

[11] Id. (internal quotation marks omitted).

[12] Id. at *15.

[13] Id. at *16.

[14] Id. at *17.

[15] See id. at *17-*18; see also id. at *22

[16] Id. at *18.

[17] Id. at *16-*17.

[18] Id. at *18.

[19] Id. at *22.

[20] Id.

[21] Id. at *30-*31.

[22] Id. at *31

[23] Id. at *21 n.81.

[24] Id. at *31-*33 (emphasis added).

[25] 136 S. Ct. at 2004