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Health Care Enforcement Review And 2017 Outlook: Part 2

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Law360, New York (January 17, 2017, 11:21 AM EST) -- In part 1 of this four-part series, we examined the U.S. Food and Drug Administration's wide-ranging enforcement activities related to health care fraud. Here, part 2 will discuss 2016's major case developments in health care enforcement.

In 2016, courts around the country heard cases involving a variety of False Claims Act and other enforcement-related matters, and going forward these case law developments are expected to have an impact on both the scope of FCA liability and the means by which FCA liability can be proven at trial. We have selected several notable 2016 court decisions that undoubtedly will affect the health care industry in 2017 and beyond.

Supreme Court FCA Decision Leads to Brawl in Lower Courts

Perhaps the most important case law development in 2016 was the U.S. Supreme Court's long-awaited, unanimous decision in Universal Health Services v. United States ex rel. Escobar. As discussed in a previous blog post and a more in-depth advisory, in Escobar the court addressed a critical issue in FCA jurisprudence — the viability and scope of the implied false certification theory of liability.

Much to the chagrin of the health care enforcement defense bar, the court validated the implied false certification theory by holding that FCA liability can attach when (1) "the claim does not merely request payment, but also makes specific representations about the goods or services provided,"; and (2) the defendant's "failure to disclose noncompliance with material statutory, regulatory or contractual requirements makes those representations misleading half-truths." At the same time, the court limited the FCA's scope by imposing a "rigorous" and "demanding" standard of materiality and explicitly rejecting the government's "extraordinarily expansive view of liability." The court held that the defendant must both knowingly violate a material requirement and know that the requirement is material to the government's payment decision.

In late June, we published a blog post discussing three FCA cases that the Supreme Court remanded back to their respective circuit courts in light of its Escobar decision. As of mid-December, at least six U.S. courts of appeal and 23 federal district courts have issued decisions on Escobar-related motions filed by defendants, and such motions are pending in other significant cases across the country. On remand, the First Circuit held in Escobar that it had "little difficulty" finding that the relator's claims alleging that the mental health clinic operator's alleged violation of licensing standards were material to the Medicaid payments. Likewise, post-Escobar, other circuits have decided that the U.S. Department of Justice and relators have adequately pled implied false certification claims.

For example, in a higher education case the Eighth Circuit held that a college's alleged violations were material to the federal aid program payments. And the D.C. Circuit held that a home health care provider failed to comply with a "central condition" of reimbursement because it did not have health care plans prepared by a physician in its patient files and that compliance with this requirement was material to the government's payment decision. In contrast, the Fourth, Ninth and Seventh Circuits each ruled that a relator's allegations failed Escobar's materiality test.

Finally, decisions are forthcoming in three notable appellate cases related to implied false certification — the Trinity Industries case in the Fifth Circuit and two cases that the Supreme Court vacated and then remanded back to the respective circuit courts after it decided Escobar.

The DOJ has routinely filed statements of interest in post-Escobar litigation that use certain language from Escobar to take an expansive view of the implied false certification theory. According to the DOJ, Escobar did not abolish much of the pre-existing case law on implied certification, including that established by the First and Ninth Circuits. For example, the DOJ has argued that Escobar "reaffirmed" prior case law finding that "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property," and that "materiality is a flexible standard that can be met in a variety of circumstances."

Further, in the DOJ's view, the materiality standard is somewhere in between "could have denied payment" and "would have denied payment" under the actual alleged facts. According to the DOJ, the materiality test does not require proof that the government would have denied payment; the test is whether the requirement is important to the government's decision-making process and whether the government would want to consider it, to be determined by many factors. Such factors include whether the requirement is labeled a condition of payment, whether it is part of the essence of a claim, whether the violation is pervasive, and whether payment has been denied in similar circumstances. The DOJ has made clear that anti-kickback statute (AKS) or Stark Law violations are material under the Escobar standard and thus could give rise to implied certification liability. At this time, little has been said regarding the separate Escobar element that the requirement must be material, and the defendant must have known that the requirement was material to the government's payment decision. Surely this new element of an FCA claim created by Escobar will be central to summary judgment decisions.

In 2017, the federal courts likely will adopt a wide range of approaches to interpretation of the materiality requirement due to Escobar's lack of clarity on this point. Fueling this fire will be a continued wave of Escobar-related motions filed by defendants seeking dismissal as well as summary judgment in cases filed before and after Escobar. The DOJ and relators will undoubtedly oppose these motions by arguing that liability is based on express false certifications, and does not depend on an implied false certification theory of liability. The DOJ and relators will also continue to argue that in any given case the alleged violation was material to the government's decision to pay the claim. Under the Escobar framework, disputes are certain to arise regarding whether a provider made any "specific representations" that were false, or failed to disclose noncompliance with statutory or other requirements. In addition, the DOJ and relators are likely to engage in robust — and contested — discovery efforts seeking information regarding whether the government did or would have actually paid claims if it had known of the alleged noncompliance. Finally, we can expect increased difficulties in settling matters in the event that the DOJ or relators, and providers, have divergent views of materiality and the matters cannot be resolved pre-litigation or at an early stage of litigation.

The AKS' Exception and Safe Harbor for Discounts Takes Heavy Fire

Two cases in the Massachusetts federal district court have sparked a vigorous debate over the application of the discount exception and safe harbor under the AKS, with both the government and the Pharmaceutical Research and Manufacturers of America (PhRMA) weighing in to assert their views.

In one case, the court allowed FCA claims — based on allegations that discounts violated the AKS — to proceed to trial, rejecting the defendant's contention that it met the statutory exception and regulatory safe harbor permitting discounts.

In United States ex rel. Banigan v. Organon USA Inc., et al., the court denied defendant Omnicare Inc.'s motion for summary judgment, finding that Omnicare did not demonstrate (at least at the summary judgment stage) that it met the AKS statutory discount exception or the regulatory safe harbor for discounts provided to Omnicare by drug maker Organon USA Inc. Specifically, the court decided that as to the statutory exception, "Omnicare has offered not an iota of evidence that the discounts were reflected at all, much less 'appropriately,' in its charges to Medicaid. As to the regulatory safe harbor, Omnicare has not shown, nor can show, that it made the relevant disclosures pursuant to a governmental investigation," as there was no investigation during the relevant time. In response, Omnicare asked the court to reconsider its decision, or to certify the court's finding for immediate interlocutory appeal, because Omnicare cannot satisfy the court's reading of the discount safe harbor where the government did not make a request for documentation of the discounts and rebates. In other words, the obligation to disclose information about a discount to the government only arises if the government asks for the information. The motion remains pending.

Similarly, in a separate case, the same judge found that a defendant failed to show that it met either the discount exception or the safe harbor. The court denied a motion to dismiss filed by CCS Medical Supplies Inc., which allegedly received discounts from a manufacturer that were fixed at the time of sale in exchange for CCS Medical's "soft campaign" to move patients to the manufacturer's products. CCS Medical argued that the relators had not sufficiently alleged an AKS violation because, among other things, discounts are protected by the discount statutory exception and safe harbor, and there were no allegations that discounts were not properly disclosed to Medicare. In denying the motion, the court held that the complaint contained no allegation that CCS Medical met the "second element" of either the discount exception or safe harbor: "that the discounts be appropriately reflected in the costs claimed or charges made to a federal health care program *or that CCS has provided certain information to a governmental agency pursuant to its request"* (emphasis added). CCS Medical moved for reconsideration, and the court later amended its decision to strike the italicized language above.

PhRMA took the rare step of filing an amicus brief in support of CCS Medical because the court's interpretation of the discount exception and safe harbor could have broad implications for "discount arrangements that are ubiquitous within the health care sector." According to PhRMA, both the discount exception and safe harbor protect all discounts, including those linked to market share, volume or formulary requirements. PhRMA asserted, as did CCS Medical, that the discount safe harbor requires an entity to provide information about a discount "*only* 'upon request' by the government" (emphasis in original). The court apparently accepted this argument, and amended its prior decision as noted above.

Although the government declined to intervene in the qui tam lawsuit against CCS Medical, it filed a statement of interest as part of the briefing on CCS Medical's motion to dismiss. The government took the position that a price reduction contingent on the discount recipient taking affirmative steps (e.g., a promotional or conversion campaign) to generate additional business for the manufacturer is not a protected discount under the AKS: "if CCS and [the manufacturer] agreed that CCS would undertake patient conversion and referral activities in return for [the manufacturer] granting price concessions, ... such an agreement would not be a 'discount' at all and would violate the AKS."

PhRMA responded to the government's statement of interest, arguing that the government's position amounted to "regulation through litigation" and raised constitutional problems. According to PhRMA, due process prohibits the government from "adding new terms to the safe harbor — or from carving out certain types of discount arrangements from the safe harbor — in a litigation brief when the defendants did not have advance notice of the government's position and an opportunity to respond."

These court decisions, taken together with the DOJ's statement of interest, have created significant uncertainty regarding long-standing, common industry discount arrangements in the pharmaceutical and other industries. The outcome of these cases therefore could have a profound effect on existing as well as future discount arrangements. At least for now, stakeholders should analyze such discount arrangements based on compliance with the exception/safe harbor, and also consider the additional criteria identified in DOJ's statement of interest.

Ruling on Proof of Falsity in Medical Necessity Cases Expected in 2017

A federal district court decision in 2016 dealt an important blow to the government's ability to prove falsity in FCA cases premised on a lack of medical necessity. We blogged about this case, United States ex rel. Paradies v. AseraCare Inc., in April and it is certainly one to watch in 2017 given that the government has appealed to the Eleventh Circuit, seeking review of the lower court's decision on the summary judgment and on certain other procedural matters.

The AseraCare case stemmed from allegations that AseraCare, a hospice provider, billed Medicare for hospice services for patients who were ineligible for end-of-life care, notwithstanding certifications of hospice eligibility from physicians. After a series of surprising procedural twists and turns (including bifurcation of the trial for purposes of determining falsity and knowledge of an FCA violation), the court decided, sua sponte, in favor of AseraCare on summary judgment after the jury found that 104 of 121 medical records were "false" (i.e., the patients were ineligible for the benefit). The court took this somewhat unprecedented step based on the fact that the government's proof on the falsity element failed as a matter of law. According to the court, if "all that exists is a difference of [medical] opinion," there can be no "falsity" under the FCA.

The court went on the explain that "this case boils down to conflicting views of physicians about whether the medical records support AseraCare's certifications that the patients at issue were eligible for hospice care. When hospice certifying physicians and medical experts look at the very same records and disagree about whether the medical records support hospice eligibility, the opinion of one medical expert alone cannot prove falsity without further evidence of an objective falsehood." The court also expressed concern that "allowing a mere difference of opinion among physicians alone to prove falsity would totally eradicate the clinical judgment required of the certifying physicians."

The AseraCare court was not the first or the only court to decide that claims are not "false" under the FCA when the alleged falsity is based on a retrospective difference of clinical opinion of eligibility for a benefit based on a medical record. For example, in United States ex rel. Morton v. A Plus Benefits Inc., the Tenth Circuit dismissed FCA allegations due to clinical disagreement that lacked an "objectively verifiable fact." Likewise, in United States v. Prabhu, the U.S. District Court for the District of Nevada granted summary judgment on FCA claims, explaining that "to demonstrate that … claims are 'known to be false' [relators] must demonstrate that there were 'lies' — and not merely a scientific or technical dispute."

These decisions hopefully signal growing resistance by the courts to the attempts of the government and relators to bring FCA cases based on one medical expert's disagreement with the treating health care provider's clinical decision making. The Eleventh Circuit has yet to hear arguments in the AseraCare appeal, but we hopefully will learn in 2017 whether AseraCare is the exception or the rule in future medical necessity cases.

Statistical Sampling to Prove Liability: Dead or Alive?

Over the past few years, the DOJ and relators have pushed for use of statistical sampling to prove liability in FCA cases. In DOJ's view, statistical sampling is essential in cases involving large numbers of potentially false claims to ensure that a provider cannot minimize FCA liability in the case of a large-scale fraud. A couple of cases in particular have garnered recent attention because they might determine whether statistical sampling can be used to demonstrate liability, rather than just to calculate damages. While federal district courts are seeing these cases with increasing frequency, no appellate court has addressed this issue.

In United States ex rel. Michaels v. Agape Senior Community Inc., et al., relators alleged that Agape, a chain of nursing homes, submitted false claims to Medicare and Medicaid for hospice services in violation of the FCA. After the government declined to intervene, the relators asked the court to allow their experts to review a small percentage of the 50,000 claims submitted by Agape during the time period at issue and then extrapolate the percentage of false claims in the small sample to the entire universe. The relators cited the expense of having their experts review each of the 50,000 claims (estimated to be about $36 million) as the reason for their request.

In response, the judge scheduled what he called a "bellwether" jury trial, during which the parties

would each present their case related to a sample of 95 patients. The court believed that such a trial was appropriate because "each and every claim at issue in [the] case [was] fact-dependent and wholly unrelated to each and every other claim." Before the trial even began, the parties agreed upon a settlement amount of $2.5 million to which the government objected. Based on its use of statistical extrapolation to identify the universe of potential claims, the government believed that the proposed settlement amount was too small because the total potential damages were around $25 million.

The district court ultimately certified two questions to the Fourth Circuit, including whether the use of statistical sampling to prove liability and damages was appropriate and whether the government has an unreviewable veto over a proposed settlement in a declined case. The Fourth Circuit agreed to review the rulings and was poised to be the first appellate court to rule on the use of statistical sampling to establish liability in FCA cases. However, during oral arguments in October 2016, the court suggested that a decision on statistical sampling might be premature — a suggestion with which the government agrees. The Fourth Circuit has yet to issue a decision in this case.

In United States et al. v. Life Care Centers of America Inc., et al., the government's reliance on statistical sampling to establish FCA liability drew considerable public attention. The government alleged that Life Care, a nursing home chain, billed Medicare for services that were not medically necessary. Due to the large number of claims at issue, the government argued that its expert should be allowed to review a random sample of 400 patient admissions (out of more than 50,000) to determine liability. Despite Life Care's objections to this approach, the court decided in the DOJ's favor at the motion to dismiss stage. The court acknowledged that using "statistical sampling to find liability for extrapolated claims could be in conflict with the government's burden to establish the elements of a FCA claim," and reserved all rights to further evidentiary challenges to the methodology and reliability of statistical sampling.

Given that Life Care agreed to pay $145 million to settle its case in October 2016, the health care industry still has no answer regarding whether the government can prove liability through statistical sampling. While the Fourth Circuit's decision in Agape may be issued in 2017, a decision favoring the health care industry seems unlikely given the court's apparent reluctance to definitively address the issue.

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