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Hospice Providers Remain Squarely in Government's Enforcement Crosshairs

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On July 8, 2020, the United States Attorney's Office for the Middle District of Florida announced that Hope Hospice agreed to pay $3.2 million to resolve a *qui tam* whistleblower action under the federal False Claims Act (FCA).[1] The settlement resolved allegations that Hope Hospice knowingly submitted false claims to Medicare for hospice services for patients who were not terminally ill. In addition to agreeing to pay $3.2 million, Hope Hospice agreed to enter into a Corporate Integrity Agreement, wherein Hope Hospice agreed to implement certain compliance-related and reporting measures.

The Hope Hospice settlement is the latest of many hospice-related FCA investigations and settlements in recent years. In fact, there have been several other seven-figure hospice-related FCA settlements just this year, including two settlements in March 2020 — one with STG Healthcare for $1.75 million,[2] and one with AseraCare for $1 million.[3]

Hospice providers have long been a focus of government enforcement scrutiny. Hospice-related government investigations tend to focus on one, or a combination of, the following areas: the compensation paid by the hospice provider to medical directors; gifts and other remuneration to referral sources such as nursing homes, hospitals, and physician offices; and whether the hospice's certifications of hospice eligibility are, in fact, appropriate under Medicare's hospice eligibility criteria. The remainder of this article will discuss these three, often inter-related areas of scrutiny.

Compensation Paid to Medical Directors

As with any financial arrangement between a healthcare entity and a referral source, financial relationships between hospice providers and medical directors have the potential to implicate the prohibitions contained in the federal Anti-Kickback Statute (AKS).[4] The AKS makes it a crime to solicit, receive, offer, or pay any remuneration in return for federal healthcare program referrals, or in return for "purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." A medical director who certifies a patient as hospice eligible makes a "referral" for purposes of the AKS.[5]

The AKS is an intent-based statute, meaning that one does not violate the statute unless he or she has unlawful intent, or the general intent to do something the law forbids.[6] Moreover, if an arrangement falls within one of a number of AKS' voluntary "safe harbors," it will be protected from criminal, civil, and administrative liability. Arrangements between hospice providers and their medical directors can (and, as a matter of best practice, should) be designed to fall within a safe harbor. The most common safe harbor that applies to such arrangements is the personal services and management contracts safe harbor. That safe harbor requires, among other things, that the

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arrangement be set out in writing, signed by the parties, be for a term of at least one year, and that the compensation paid to the medical director be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of any federal healthcare program referrals or business.[7] Another safe harbor that could apply is the employment safe harbor, which exempts from AKS liability any remuneration paid by an employer to a bona fide employee.[8]

Any arrangement between a hospice provider and a medical director that does not fall within one of these safe harbors is likely to garner scrutiny by government enforcers. If "any one purpose" of the remuneration paid by the hospice provider to the medical director is to induce federal healthcare program referrals,[9] then both the hospice provider and the medical director could face criminal, civil, and administrative liability under the AKS and related statutes and regulations.

Remuneration to Referral Sources

Another area of government scrutiny as it relates to hospice providers is the giving of gifts or other types of remuneration to referral sources, such as nursing homes, hospitals, and physician offices. In the often dog-eat-dog world of hospice marketing, the hospice provider that does not engage in aggressive marketing risks losing out on valuable referral relationships. For that reason, many hospice providers are incentivized to provide marketing gifts and other types of remuneration to actual and potential referral sources.

As discussed above, however, if "any one purpose" of such remuneration is to solicit federal healthcare program business, the AKS comes into play. The problem arises when one considers the following questions: why would a hospice provider send a gift to a potential referral source for any reason *other than* to induce referrals? Complicating matters, the AKS does not contain a *de minimus* exception. That means that, technically speaking, something as commonplace as a marketing lunch of sandwiches and cookies for a referring nursing home could potentially implicate the AKS. As the Office of Inspector General for the U.S. Department of Health and Human Services (OIG) has stated in one of its guidance documents, "[i]n some industries, it is acceptable to reward those who refer business to you. However, in the Federal health care programs, paying for referrals is a crime."[10]

Despite the absence of a *de minimus* exception, the OIG has generally taken the position that "nominal" gifts do not cause concern under the AKS.[11] Unfortunately, however, the OIG has not defined "nominal" for purposes of the AKS.[12] Accordingly, while any gift to a referral source or potential referral source could *potentially* implicate the AKS, things such as modest lunches or marketing trinkets such as pens, coffee mugs, or paper weights are not likely to garner serious AKS scrutiny.

Allegations of Improper Hospice Eligibility Certifications

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Another area of government scrutiny that is common in hospice-related investigations is whether patients who are certified as hospice eligible meet Medicare's criteria for hospice eligibility. To be eligible for hospice care under Medicare rules, an individual must be certified as being "terminally ill," which means that the individual's life expectancy is six months or less "if the illness runs its normal course." [13] A physician must certify a patient as hospice eligible for two initial 90-day benefit periods, and then every 60 days thereafter.

Perhaps more than any other area of medicine, whether a patient is "terminally ill" for purposes of hospice eligibility is, by definition, often subjective. Even the Department of Health and Human Services (HHS) itself has acknowledged that "[p]redicting life expectancy is not an exact science," and that, sometimes, patients with an initial prognosis of terminality can improve over time.[14] For this reason, courts have held that a clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed "false" for purposes of the FCA when there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion, with nothing more.[15]

Nevertheless, in hospice-related investigations, the government often focuses on whether the hospice provider was appropriately certifying patients for hospice eligibility. One of the data points that the government focuses on is the hospice's "live discharge" rate (i.e., the percentage of patients that are deemed hospice eligible and then are subsequently discharged alive). According to a 2018 paper published by the Centers for Medicare & Medicaid Services (CMS), while the "national rate of live discharge from hospice has declined in recent years . . . concerns about live discharge persist."[16] In 2016, for example, "25% of [hospice] providers had live discharge rates greater than 31% and 10% of providers had rates greater than 53%."[17] Despite HHS' recognition that predicting life expectancy is not an exact science, hospice providers with very high live discharge rates are at higher risk for audits or investigations.

Scrutiny related to the appropriateness of hospice eligibility certifications is often tied to scrutiny related to the compensation paid by the hospice provider to the certifying physician, often times the hospice's medical director. A common theory of liability by the government is that unlawful kickbacks to certifying physicians (i.e., incentives for those physicians to certify patients as hospice eligible even where they may not meet Medicare's hospice eligibility criteria) could be disguised as legitimate payments to medical directors. As discussed above, if the compensation paid by a hospice provider to a medical director does not meet all of the safe harbor requirements, including if it is in excess of fair market value or tied in any way to the volume or value of federal healthcare program referrals, this theory of liability is often successful and can lead to significant settlements and judgments.

Conclusion

Despite some recent legal setbacks in hospice-related fraud investigations (e.g., the Eleventh Circuit's decision in *AseraCare*), the government does not appear to have given up, or really even slowed down, in pursuing such investigations against hospice

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providers. Because hospice providers remain a focus of government enforcement scrutiny, such providers must remain vigilant in ensuring compliance with the myriad of federal rules and regulations, particularly when it comes to their relationships with medical directors and referral sources, and their eligibility certification process.

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[1] 31 U.S.C. § 3729 *et seq*. The DOJ's announcement can be accessed at https://www.justice.gov/usao-mdfl/pr/hope-hospice-agrees-pay-32-million-settle-false-claims-act-liability.

[2] https://www.justice.gov/usao-ndga/pr/hospice-pay-175-million-resolve-false-claims-act-allegations.

[3] https://www.modernhealthcare.com/legal/aseracare-pay-1-million-settle-false-claims-act-case. The AseraCare settlement came soon after the Eleventh Circuit Court of Appeal's much-anticipated decision in *United States v. AseraCare*, 938 F.3d 1278 (11th Cir. 2019), discussed in more detail below.

[4] The AKS is found at 42 U.S.C. § 1320a-7b(b). The related Stark Law, found at 42 U.S.C. § 1395nn, does not apply to hospice services, as those services are not considered "designated health services" under the Stark Law. 42 C.F.R. § 411.351. That being said, if a hospice provider provides non-hospice palliative services, such as laboratory services, physical therapy, or imaging services, those services may, in fact, be subject to the Stark Law.

[5] *See, e.g., U.S. v. Patel*, 17 F. Supp. 3d 814 (7th Cir. 2014).

[6] *See, e.g., U.S. v. Starks*, 157 F.3d 833 (11th Cir. 1998).

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[7] 42 C.F.R. § 1001.952(d).

[8] *Id.* § 1001.952(i).

[9] *See, e.g., U.S. v. Kats*, 871 F.2d 105 (9th Cir. 1989) and *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985).

[10] HHS-OIG, *A Roadmap for New Physicians: Fraud & Abuse Laws*, *available at* https://oig.hhs.gov/compliance/physician-education/01laws.asp.

[11] *See, e.g.,* OIG Compliance Program for Individual and Small Group Physician Practices, 65 Fed. Reg. 59441 (2000) (stating that "[s]oliciting, accepting or offering any gift or gratuity of more than nominal value to or from those who may benefit" from a federal healthcare program referral may constitute a violation of the AKS).

[12] Although the OIG has never stated what it would consider "nominal" under the AKS, it has defined "nominal value" in a similar context: the general prohibition against beneficiary inducement. There, the OIG has stated that non-monetary gifts to a beneficiary that have a retail value of $15 or less (or $75 in the aggregate over a 12-month period) are exempt from the beneficiary inducement prohibition. 81 Fed. Reg. 88368, 88394 (2016).

Similarly, the Stark Law contains an exception for non-monetary compensation from an entity to a physician that does not exceed a certain amount per calendar year. *See* 42 C.F.R. § 411.357(k). In 2020, that limit is $423. https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/CPI-U_Updates. While, as discussed above, the Stark Law does not apply to the hospice benefit, some health law practitioners look to this provision as a measure of "nominal" value according to HHS.

[13] Medicare Benefit Policy Manual, Ch. 9., Section 10.

[14] 75 Fed. Reg. 70372, 70488 (2010).

[15] *See, e.g., U.S. v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019). Although the Eleventh Circuit reversed the district court's order, which sua

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sponte granted summary judgment in favor of the hospice provider after a jury had already found for the government, the court's decision in *AseraCare* is widely viewed as a significant victory for FCA defendants, particularly in the hospice realm. That is because the court held that "the mere difference of reasonable opinion between physicians, without more, as to the prognosis for a patient seeking hospice benefits does not constitute an objective falsehood" under the FCA. *Id.* at 1301.

[16] Draft Measure Specifications: Transitions from Hospice Care, Followed by Death or Acute Care (CMS, March 2018), *available at* *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Development-of-Draft-HQRP-Transitions-Measure-Specifications.pdf*.

[17] *Id.*

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