The Salcido Report False Claims Act Public Disclosure Alert

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OIG Joint Venture Advisory Opinion Does Not Consider Multiple Court Decisions That Undermine the Conclusions in its Opinion

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Key Points

- HHS-OIG recently issued an Advisory Opinion finding that proposed JV, if undertaken, could constitute prohibited remuneration under the AKS.
- The scope of material the OIG may consider is limited. The OIG does not opine regarding the intent of the Requester and does not, and cannot under its rules, address defenses recognized under related laws like the FCA in which courts have construed the scope of the AKS.
- If the parties to the arrangement do not have an intent to engage in wrongful conduct and all payments are made at fair market value, the parties to the JV should have dispositive defenses to any contention that they violated the AKS or FCA under multiple court decisions that the OIG did not, and cannot, consider.

On November 17, 2021, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued Advisory Opinion 21-18 (the "Advisory Opinion" or "Opinion"). The OIG concluded that the proposed joint venture (JV) arrangement between a therapy services company and a company that owns skilled nursing facilities (SNFs), if undertaken, could generate prohibited remuneration under the Anti-Kickback Statute (AKS) "if the requisite intent were present."[1] The OIG observed that its Opinion reflected its longstanding concern regarding JV arrangements, "especially where all or most of the business from the joint venture is derived from one of the joint venture investors."[2]

The OIG's Advisory Opinion is only binding on the Requester, and not other members of the public, and it offers little guidance to everyone else in structuring JVs.[3] Under the AKS, two critical elements are whether "remuneration"—that is, some amount other than fair market value—was paid and whether the party "knowingly and willfully" engages in wrongful conduct.[4] OIG Advisory Opinions do not address these two elements.[5] Further, a primary enforcement device for the AKS are actions filed under the False Claims Act (FCA). OIG Advisory Opinions do not express any opinion regarding potential exposure to liability under the FCA.[6]

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As a result of these gaps in guidance, OIG Advisory Opinions do not address, in the context of a JV arrangement, FCA court decisions interpreting the scope of the AKS that find there is no violation of the AKS when all payments are made at fair market value. For example, multiple courts, including a circuit court, have ruled that if fair market value is exchanged, there cannot be any unlawful remuneration exchanged under the AKS and hence no FCA violation in actions asserting the FCA was breached because of an underlying AKS violation.[7] Further, a half dozen FCA appellate cases have ruled that if the governing law is ambiguous—such as whether a fair market value payment can be unlawful remuneration under the AKS—and no official governmental guidance exists to warn defendant away from a reasonable interpretation, there cannot be a violation of the FCA.[8]

Set forth below is the OIG's policy guidance regarding suspect JVs, including its recent guidance in Advisory Opinion 21-18. Also set forth is a detailed discussion of FCA / AKS case law addressing what constitutes unlawful remuneration for purposes of the AKS and, under what circumstances, one can knowingly breach a governmental rule when the governing rule itself is ambiguous, case law the OIG did not consider in rendering its Opinion. What this analysis shows is that, if the current case law is taken into account, rather than the necessarily myopic view the OIG must take, there should not be any legal impediment to properly structured JV arrangements that are based upon fair market value payments when the parties do not have any intent to engage in wrongful conduct. Indeed, in the one case the Department of Justice pursued regarding an alleged suspect contractual JV similar to what the OIG describes in its Advisory Opinion, defendants prevailed at trial.[9]

OIG's Guidance Regarding JVs

The OIG, in continuous guidance, over 30 years, has expressed concerns regarding JVs, especially where all or most of the business from the JV is derived from one of the JV investors.[10] Over this period, neither Congress nor HHS has enacted a law prohibiting this business structure. Courts generally do not provide substantial deference to agency policy statements.[11] Similarly, "OIG advisory opinions do not establish rules of decision, and are not to receive judicial deference."[12]

OIG Fraud Alert

Related to JVs, the OIG published a Special Fraud Alert indicating various features that it considered suspect.[13] In the Special Fraud Alert, the OIG conceded that "[o]f course, there may be legitimate reasons to form a joint venture, such as raising necessary investment capital."[14] But the OIG also warned that where the intent was not to raise investment capital, or other lawful purpose, but to "lock up a stream of referrals" from investors to compensate them indirectly for their referrals, the arrangement could result in a violation of the AKS.[15] The OIG raised the following non-exclusive list of questionable features that could raise red flags that the JV is created for an improper purpose:

- Investors are chosen because they are in a position to make referrals.
- Investors are expected to make a large number of referrals and may be offered a greater investment opportunity in the JV than those anticipated to make fewer referrals.

- Investors may be actively encouraged to make referrals to the JV, and may be encouraged to divest their ownership interest if they fail to sustain an "acceptable" level of referrals.
- The JV tracks its sources of referrals, and distributes this information to the investors.
- Investors may be required to divest their ownership interest if they cease to practice in the service area, for example, if they move, become disabled or retire.
- Investment interests may be nontransferable.
- The amount of capital invested by the referral source may be disproportionately small and the returns on investment may be disproportionately large when compared to a typical investment in a new business enterprise.
- Referral source investors may invest only a nominal amount, such as $500 to $1,500.
- Referral source investors may be permitted to "borrow" the amount of the
- "investment" from the entity, and pay it back through deductions from profit distributions, thus eliminating even the need to contribute cash to the partnership.
- Investors may be paid extraordinary returns on the investment in comparison with the risk involved, often well over 50 to 100 percent per year.[16]

OIG Advisory Opinion 21-18

Recently, on November 17, 2021, the OIG issued Advisory Opinion 21-18. Under the contemplated arrangement, a contract therapy services company that provided services at SNFs proposed to enter into a JV with a company that owns SNFs and the JV would provide therapy services to the SNFs.[17] The SNF's purchase price for its ownership interest in the JV would be based upon a third-party valuation and be consistent with fair market value.[18] The SNF would enter into a management services agreement with the JV to provide the clinical and back-office employees, space and equipment necessary of the JV's operations in exchange for a fee that is consistent with fair market value.[19] Distributions to the SNF and therapy company would be proportional to their respective ownership interests in the JV.[20] The SNF would not be involved in the day-to-day operations of the JV.[21] The JV would not have employees but would lease all clinical and back-office staff from the therapy company.[22] Under the arrangement, the SNF would not be required to contract with or make direct referrals to the JV, but it was anticipated that the SNF would do so.[23] Further, it was anticipated that at the start of the arrangement, the JV would only do business with the SNF that held an ownership interest in the JV and hence all the JV's revenues would likely be generated through its agreements with the SNFs.[24] The JV would bill the SNFs for its services and the SNFs would pay the JV fair market value for the JV's services.[25] The SNFs would bill and collect from payors, including federal health care programs.[26]

The OIG concluded that the proposed arrangement, if undertaken, "would generate prohibited remuneration" under the AKS, "if the requisite intent were present."[27] The OIG noted that it "has longstanding and continuing concerns about these types of joint venture arrangements, especially where all or most of the business from the joint venture is derived from one of the joint venture investors."[28] The OIG observed that the proposed arrangement presented "a host of concerns, including patient steering, unfair competition, inappropriate utilization, and increased costs to Federal health care

programs."[29] Specifically, the OIG noted that the SNF would be expanding into a related line of business—therapy services for patients of the SNFs—that would be, at least in the near term, dependent on referrals and business generated by the JV partner, the therapy company.[30] The SNF would not actually participate in the operation of the JV but would contract out substantially all of the JV's operations to therapy company.[31] The therapy company is an established provider of the same services that the JV would provide.[32] And, by creating the JV, the therapy company agrees to forego a portion of the profit that it would realize if it provided those services directly (as it currently did), while providing the SNF the opportunity to share in profits (assuming the venture is profitable).[33] As a result, the OIG reasoned that "there is a significant risk that the Proposed Arrangement would be used as a vehicle to: (i) reward the [SNF] for directing Federal health care program and other business to [the therapy company]; (ii) lock in that referral stream to [the therapy company]; and (iii) block out potential competitor therapy services providers."[34]

The AKS

The AKS prohibits persons from paying or soliciting remuneration to induce another to refer business reimbursed under a federal health care program. Specifically, the statute prohibits any type of payment that is "**knowingly and willfully**" intended to induce someone to refer federal health care program patients, or to order goods or services reimbursable under such programs.[35]

To establish an AKS violation, "a person or corporation must (1) offer or pay any remuneration (2) to induce another person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, and (3) do so knowingly and willfully."[36] AKS violations are classified as felonies, and are punishable by fines of up to $100,000 and imprisonment for up to 10 years.[37]

In determining whether there is a possible violation of the AKS regarding the proposed transaction, there are two key elements for analysis. First, whether "remuneration" is being exchanged between the SNF and the JV, the JV and the therapy company, or the SNF and the therapy company. Second, if so, whether the remuneration allegedly paid is made "knowingly and willfully" in violation of the AKS.

Remuneration Under the AKS

Plaintiff must establish the payment of unlawful "remuneration" to prove an AKS violation. The Medicare Act broadly defines "remuneration" as "transfers of items or services for free **or for other than fair market value**,"[38] and one appellate court, in *Bingham v. HCA, Inc.*, recently ruled that this definition of remuneration indicates that fair market value transactions do not breach the AKS.[39]

Specifically, in *Bingham*, the 11th Circuit noted that an AKS violation "requires that there be 'remuneration' offered or paid in the transaction at issue."[40] In *Bingham*, the plaintiff claimed that defendant violated the AKS by providing sweetheart deals to certain physicians who leased space in medical office buildings the defendant developed in exchange for patient referrals from these physicians.[41] In defining remuneration, the court looked to Black's Law Dictionary, which construes "remuneration" in pertinent part as "[p]ayment; compensation."[42] Compensation, in turn, "cannot be given unless some sort of benefit is conferred."[43] In light of these

definitions, remuneration is only provided when there is a benefit and "the value of a benefit can only be quantified by reference to its fair market value."[44] The court also noted that this "understanding of 'remuneration' is supported by the definition of 'remuneration' in 42 U.S.C. § 1320a-7a(i)(6), which relates to civil monetary penalties in connection with medical fraud."[45] The court noted that although this definition of remuneration is in a different section of the statute, "it also defines 'remuneration' to include the 'transfer[] of items or services for free or for other than fair market value' and thus is consistent with our view of the correct definition."[46]

Given the dictionary definition of remuneration and its definition in a related statutory provision, the court concluded that "the issue of fair market value is not limited to" defendant's safe harbor defense, "but is rather something [plaintiff] must address in order to show that [the defendant] offered or paid remuneration to physician tenants."[47] The court affirmed the district court's grant of summary judgment because the relator did not show that any of the arrangements conferred any benefit in excess of fair market value.[48]

Knowing or Willful Conduct under the AKS

As a long series of cases hold, to establish that defendants knowingly and willfully paid remuneration to induce referrals, the plaintiff must establish, at a minimum, that defendants knew that their conduct is wrongful.[49]

A defendant does not violate the AKS by merely desiring to obtain referrals from a business arrangement that is designed for other purposes.[50]

Courts have identified multiple factors that specify when defendants do not act with unlawful intent. For example, several AKS cases illustrate that where defendants operate in good faith, participate in common industry practices, and engage in actions that are consistent with legitimate business purposes, there is no violation of the AKS.[51]

Application of the AKS to Facts Underlying the OIG's Advisory Opinion

As noted, when FCA case law construing the AKS is taken into account, the conclusions underlying the OIG's Advisory Opinion are fundamentally undermined. This is because when fair market value is exchanged, there is no unlawful remuneration under the AKS. Moreover, when one relies upon a reasonable interpretation of law—such as the 11th Circuit's ruling that payments at fair market value do not violate the AKS—there can be no FCA violation, let alone an AKS violation, which has a more stringent intent requirement, unless there is official governmental guidance to warn a defendant away from its reasonable interpretation. That is, if the current case law is taken into account, rather than the constricted universe of material that the OIG is confined to consider, there should not be any legal impediment to properly structured JV arrangements that are based upon fair market value payments when the parties do not have any intent to engage in wrongful conduct.

No Remuneration Exists

When all payments will be at fair market value, there is not unlawful remuneration under the AKS.

Under the Medicare Act and some FCA / AKS court decisions, the payment of fair market value does not constitute remuneration under the AKS.[52] If there is no remuneration being exchanged for purposes of the AKS, there cannot be a violation of the AKS.

No Unlawful Intent

As with FCA case law, another issue the OIG does not consider as part of its Advisory Opinion is the parties' intent. But aside from no remuneration being present, there is no unlawful intent under FCA case law, let alone the AKS. This is true for at least two reasons.

First, courts rule that defendants do not knowingly submit false claims when they act within a reasonable interpretation of what is, at most, an ambiguous law and when there is no official governmental guidance, such as a court of appeals decision or binding agency determination, which would warn defendants away from their reasonable interpretation.[53]

Here JV partners would be able to demonstrate that they could not act with the requisite scienter to violate the AKS because they have a reasonable interpretation of the law in light of *Bingham* and the Medicare Act's definition of remuneration that any payments set at fair market value do not constitute unlawful remuneration under the AKS. Further, they would be able to assert that there is no "official" governmental guidance to warn them away from their reasonable interpretation. Courts generally rule, in FCA actions, that to constitute official governmental guidance, the guidance must be from an appellate court decision or a binding agency pronouncement.[54] OIG policy statements, such as Special Fraud Alerts or Bulletins, are not binding agency precedent.[55] Thus, until Congress enacts a statute prohibiting these types of arrangements, or HHS promulgates a regulation, or appellate courts reject the position of those entering into these types of JVs that fair market value transactions do not breach the AKS, JV partners exchanging fair market value should have a dispositive defense.[56]

Second, providers entering into JVs also potentially have meritorious arguments that they are not acting with the requisite scienter to breach the AKS because when the arrangement is at fair market value, reflect common industry arrangements, are consistent with common industry practices, courts typically find no violation of the AKS.[57] Potential steps the parties identified in the Advisory Opinion may undertake to further manifest that they have no intent to violate the AKS include ensuring that the proposed JV does not require that the SNF refer business to the JV; the SNF owner's investment is not contingent upon the SNF referring any business to the JV; the SNF investor's ownership interest in the JV will not be reduced if any referrals fall below any targeted amount; the SNF owner's investment will not be nominal; the SNF investors will not borrow the amount of its investment from other investors in the JV; all items and services related to the JV will be paid at fair market value, and any return the SNF investor makes will be proportional to the capital invested in the JV.

Conclusion

Oddly, as part of the Advisory Opinion process, the OIG is compelled to ignore the very case law that demonstrates that its Opinion is mistaken. When that case law is considered and followed, it appears that there should not be any legal impediment to

properly structured JV arrangements that are based upon fair market value payments when the parties do not have any intent to engage in wrongful conduct.

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[1] *See* HHS-OIG Adv. Op. 21-18 at 1. Specifically, the Requestor is a contract therapy services company that provides management of day-to-day operations and therapy staffing for rehabilitation programs in long-term care communities, including SNFs, assisted living facilities, and full-service continuing care retirement communities (collectively "Facilities"). Under the Proposed Arrangement, Requestor would enter into a JV venture with a company that directly or indirectly owns Facilities, and the JV entity would provide contract therapy services to rehabilitation programs in Facilities.

[2] *Id*. at 5.

[3] 42 C.F.R. §1008.53 ("An advisory opinion issued by the OIG will have no application to any individual or entity that does not join in the request for the opinion. No individual or entity other than the requestor(s) may rely on an advisory opinion").

[4] *See, e.g., Bingham v. HCA, Inc.*, 783 F. App'x 868 (11th Cir. 2019) (describing law).

[5] *See generally* 42 C.F.R. §1008.53(b) ("The OIG will not address through the advisory opinion process - (1) What the fair market value will be, or whether fair market value was paid or received, for any goods, services or property").

[6] *See, e.g., id*. § 1008.59(a) ("The OIG will not provide any legal opinion on questions or issues regarding an authority which is vested in other Federal, State or local government agencies"); see also Adv. Op. 21-18 at 8 ("We express no opinion herein regarding the liability of any person under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct").

[7] *See, e.g., Bingham*, 783 F. App'x at 870-73; *U.S. ex rel. Jamison v. McKesson Corp.*, 900 F. Supp. 2d 683, 699-700 (N.D. Miss. 2012); *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 678-79 (N.D. Ill. 2006).

[8] *See, e.g., U.S. ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455, 472 (7th Cir. 2021); *United States v. Allergan, Inc.*, 746 F. App'x 101, 109-10 (3d Cir. 2018); *U.S. ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017); U*.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 880 (8th Cir. 2016); *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 289 (D.C. Cir. 2015); *U.S. ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 832 (8th Cir. 2013).

[9] *U.S. ex rel. Jamison v. McKesson*, 900 F. Supp. 2d 683 (N.D. Miss. 2012). The author of this Alert was lead counsel for the prevailing SNF defendants in this lawsuit.

[10] *See, e.g.*, OIG 1989 Special Fraud Alert on Joint Ventures Arrangements, *reprinted in* 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994); Special Advisory Bulletin: Contractual Joint Ventures (April 2003); Adv. Op. 21-18 (Nov. 17, 2021).

[11] *See*, e.g., McKesson, 784 F. Supp. 2d at 677, n. 10; *see also* Memorandum from The Assoc. Attorney Gen. to the Heads of Civil Litig. Components and U.S. Attorneys (Jan 25, 2018) (Department of Justice "litigators may not use noncompliance with guidance documents for a basis for proving violations of applicable law").

[12] *U.S. ex rel. McDonough v. Symphony Diagnostic Servs., Inc.*, 36 F. Supp. 3d 773, 780 (S.D. Ohio 2014) (citation omitted). Moreover, OIG advisory opinions, by regulation, "have no application to any individual or entity that does not join in the request for the opinion. No individual or entity other than the requestor(s) may rely on an advisory opinion." 42 C.F.R. § 1008.53. Further, "OIG's identification of a practice as 'suspect' merely triggers further investigation by OIG; it does not render a practice *per se* illegal or unlawful, as even Relator's expert acknowledges." *Symphony Diagnostic Servs.*, 36 F. Supp. 3d at 780; *see also id*. at 781 (notwithstanding relator's contention that OIG described defendant's practice as suspect in advisory opinions involving other parties, finding, under facts of case, at summary judgment that defendant did not breach AKS).

[13] *See* 59 Fed. Reg. 65,372 (Dec. 19, 1994).

[14] *Id*. at 65,373.

[15] *Id*. at 65,374.

[16] *Id*. The OIG has also published other guidance questioning suspect joint ventures. *See, e.g.*, Special Advisory Bulletin: Contractual Joint Ventures (April 2003). In that Special Advisory Bulletin, the OIG provided the following example as a "potentially problematic contractual" arrangement:

A hospital establishes a subsidiary to provide DME [durable medical equipment]. The new subsidiary enters into a contract with an existing DME company to operate the new subsidiary and to provide the new subsidiary with DME inventory. The existing DME company already provides DME services comparable to those provided by the new hospital DME subsidiary and bills insurers and patients for them.

Id.

[17] *Id*. at 2.

[18] *Id*.

[19] *Id*.

[20] *Id*.

[21] *Id*.

[22] *Id*.

[23] *Id*.

[24] *Id*. at 3.

[25] *Id*.

[26] *Id*.

[27] *Id*. at 1. The OIG noted that for "purposes of the Federal anti-kickback statute, 'remuneration' includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind." This definition is inconsistent with how the Medicare Act defines remuneration—that is, something "other than fair market value"—and inconsistent with how some courts have defined remuneration in the context of evaluating the AKS. *See* 42 U.S.C. § 1320a-7a(i)(6); *Bingham*, 783 F. App'x at 873; *see also Consol. Med. Transp.*, 458 F. Supp. 2d at 626 ("In order to prove that the Hospital Defendants violated the AKS, Relators must prove that the Hospital Defendants accepted illegal remuneration, meaning something of value, in return for referrals").

[28] *Id*. at 5. The OIG cited to its 1989 Fraud Alert. See Adv. Op. 21-18 at 5, n. 11.

[29] *Id*. at 6. The OIG cited to it 2003 Special Advisory Bulletin on Contractual Joint Ventures. *Id* at 6.

[30] *Id*.

[31] *Id*. Based on this, the OIG assumes that the SNF's "actual financial and business risk would be minimal or nonexistent because the [SNF] is in a position to control or influence the amount of business its Affiliated Facilities direct" to the JV. *Id*. Of course, this assumes that the provision of therapy is a profitable business line, that reimbursement rates from payors will continue to exceed the SNFs' costs, and that the JV will not ever experience business disruption, such as can occur during a pandemic. The IG does not, obviously, provide any citation or foundation that could support its assumption that the JV will necessarily be profitable simply because the SNF can refer therapy patients to the JV.

[32] *Id*.

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

[34] *Id*. at 7.

[35] *See* 42 U.S.C. § 1320a-7b(b).

[36] *U.S. ex rel. Gale v. Omnicare, Inc.*, No. 1:10-cv-127, 2013 U.S. Dist. LEXIS 102658 at *15 (N.D. Ohio July 23, 2013); *see also United States v. Miles*, 360 F.3d 472, 479-80 (5th Cir. 2004) (ruling that to establish a cause of action, the government must prove that defendants: (1) knowingly and willfully received remuneration; (2) as an inducement; (3) to refer an individual; (4) to another for the furnishing of an item or service paid under a federal health care program).

[37] 42 U.S.C. § 1320a-7b(b).

[38] 42 U.S.C. § 1320a-7a(i)(6) (emphasis added). *See also Miller v. Abbott Labs*, 648 F. App'x 555, 561 (6th Cir. 2016) (quoting statute); *Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 400 (6th Cir. 2015) (same). The AKS does not define "fair market value." Courts, in applying fair market value, in the AKS context, will generally define it as prices that a willing buyer and seller would exchange in an arm's-length transaction. *See, e.g., McKesson*, 900 F. Supp. 2d at 699-700 (applying generally Black's Law Dict. definition that fair market value is "[t]he price that a seller is willing to accept and a buyer is willing to pay on the open market in an arms'-length transaction"); *Consol. Med. Transp.*, 458 F. Supp. 2d at 678 (defining fair market value under the AKS as "the price a willing buyer would pay a willing seller … when neither is under compulsion to buy or sell").

[39] 783 F. App'x 868 (11th Cir. 2019).

[40] *Id*. at 873.

[41] *Id*. at 870–71.

[42] *Id*. at 873.

[43] *Id*.

[44] *Id*.

[45] *Id*.

[46] *Id*.

[47] *Id*.

[48] *Id*. at 874.

[49] *See, e.g., United States v. Starks*, 157 F.3d 833, 837-38 (11th Cir. 1998) (upholding AKS jury instruction that "[t]he word willfully . . . means the act was committed voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law"); *United States v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996) (affirming AKS jury instruction that "the word 'willfully' means unjustifiably and wrongfully, known to be such by the defendant"); *see also United States v. McClatchey*, 217 F.3d 823, 829 (10th Cir. 2000) (noting that neither the government nor defendant objected to AKS jury instruction defining willfulness as: "An act is done willfully if it is done voluntarily and purposely and with the specific intent to do something the law forbids, that is, with a bad purpose either to disobey or disregard the law. A person acts willfully if he or she acts unjustifiably and wrongly while knowing that his or her actions are unjustifiable and wrong. Thus, in order to act willfully as I have defined that term, a person must specifically intend to do something the law forbids, purposely intending to violate the law"); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (affirming an AKS jury instruction that willfully "means that the act was committed voluntarily and purposely with the specific intent to do something the law forbids; that is to say, with bad purpose either to disobey or disregard the law"); *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989) (upholding AKS jury instruction explaining that "[w]illfully means to do something purposely, with the intent to violate the law, to do something purposely that law forbids").

[50] *See, e.g., U.S. ex rel. Ruscher v. Omnicare, Inc.*, 663 F. App'x 368, 374 (5th Cir. 2016) (citation omitted) ("There is no AKS violation … where the defendant merely hopes or expects referrals from benefits that were designed wholly for other purposes."); *see also McKesson*, 900 F. Supp. 2d at 698–99 (noting that when "analyzing alleged violations of the AKS, a key distinction is that the law does not criminalize referrals for services paid for by Medicare or Medicaid—it criminalizes knowing and willful acceptance of remuneration in return for such referrals" and that "in order to violate the AKS, it is not enough to covet the business of another, there must actually be some bad intent to violate the law" and rejecting the government's AKS allegation because it "presented no proof that either party did anything illegal or in bad faith") (citations and internal quotations omitted).

[51] *See U.S. ex rel. Kosenske v. Carlisle HMA*, No. 1:05-CV-2184, 2010 U.S. Dist. LEXIS 31619, at *32 (M.D. Pa., Mar. 31, 2010) ("A defendant's good faith is a cognizable defense to claims pursued under the Anti-Kickback Act …"); *McDonnell v. Cardiothoracic & Vascular Surgical Assocs.*, No. C2-03-79, 2004 U.S. Dist. LEXIS 29436, at *27 (S.D. Ohio, July 28, 2004) (where "it is clear to the Court" that parties "proceeded in good faith" regarding the arrangement, they "lacked the specific intent to disobey the Anti-Kickback statute"); *see also U.S. ex rel. Lacy v. New Horizons, Inc.*, 348 F. App'x 421, 428-29 (10th Cir. 2009) (dismissing FCA allegation because FCA plaintiff failed to show underlying AKS violation because the plaintiff failed to show any unlawful remuneration was exchanged); *Hanlester Network v. Shalala*, 51 F.3d 1390, 1401 (9th Cir. 1995) (finding no AKS violation when management services agreement "reflects a relatively common practice in the clinical laboratory field"); *Consol. Med. Transp.*, 458 F. Supp. 2d at 675-77, 683-84 (defendants do not violate AKS when their actions are consistent with legitimate business purposes); *see generally U.S. ex rel. Conner v. Salina Reg'l Health Ctr.*, 459 F. Supp. 2d 1081, 1090 (D. Kan. 2006) (dismissing FCA action alleging a violation of the AKS when the alleged remuneration—requiring physician to provide his own operating room staff—was permitted by law), *aff'd in relevant part*, 543 F.3d 1211 (10th Cir. 2008).

[52] *See Bingham*, 783 F. App'x at 870-73; *McKesson*, 900 F. Supp. 2d at 699 ("In the context of the AKS, courts use 'fair market value' as the gauge of value when assessing the remuneration element of the offense") (citations omitted); *see also Consol. Med. Transp.*, 458 F. Supp. 2d at 679 ("Relators cannot prove that the Hospital Defendants received remuneration—something of value—without comparing the contracted rates with fair market value" and finding no violation of AKS because "Relators have failed in this regard"). *See generally U.S. ex rel. Obert-Hong v. Advocate Health Care*, 211 F. Supp. 2d 1045, 1049 (N.D. Ill. 2002) ("To comply with the statute, the hospital must simply pay fair market value for the practice's assets") (footnote omitted).

[53] *See, e.g., U.S. ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455, 472 (7th Cir. 2021) ("Because [defendant] had an objectively reasonable understanding of the regulatory definition … and no authoritative guidance placed it on notice of its error, the relators have not shown that [defendant] acted knowingly"); *United States v. Allergan, Inc.*, 746 F. App'x 101, 109-10 (3d Cir. 2018) (finding although the court was not prepared to find that the

defendants had the best interpretation of the statute, it found that the plaintiff had failed to plead an FCA cause of action because the defendants had a reasonable interpretation of an ambiguous statute and the relator did not plead that the government had published any official guidance that would "warn" defendants away from their reasonable interpretation); *U.S. ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017) (finding that scienter under the FCA could not be established because defendant's good faith interpretation of regulation was reasonable); U*.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 880 (8th Cir. 2016) (affirming dismissal because defendant had a reasonable interpretation of ambiguous rule and because there had not been sufficient "official government warning" to warn defendant away from its reasonable interpretation); *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 289 (D.C. Cir. 2015) (FCA imposes no liability for the reasonable interpretation of an ambiguous regulation in the absence of interpretive guidance "that might have warned [the defendant] away from the view it took") (citation omitted); *U.S. ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 832 (8th Cir. 2013) (defendant's "reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA.").

[54] *See, e.g., U.S. ex rel. Complin v. N.C. Baptist Hosp.*, 818 F. App'x 179, 182-84, n. 6 (4th Cir. 2020) (finding that given the "complex and highly technical regulatory" regime and because there was a lack of clarity regarding Medicare's Related-Party rule, a Medicare Provider Reimbursement Review Board determination, which is non-precedential and non-binding, is "the kind of non-authoritative guidance" that "generally is not enough to warn a regulated defendant away from an otherwise reasonable interpretation of a regulation for purposes of establishing FCA scienter") (internal quotation and citation omitted); *United States v. Safeway Inc.*, 466 F. Supp. 3d 912, 931, 939-41 (C.D. Ill. 2020) (noting that to "establish an FCA violation, the Relator must show there was a clear rule forbidding [defendant's] position at the time of the conduct" and finding that defendant "could not recklessly or knowingly violate the law between 2006 and 2015 when the law relating to the impact of membership discount and price matching programs on usual and customary prices was not clear" and there was no authoritative guidance warning defendant away from its interpretation; notably the court concluded that agency Manual guidance did not constitute "authoritative guidance" because it is not "binding on" the agency); *see generally Purcell*, 807 F.3d at 289-90 (holding oral guidance from government employee or informal letter from government staff member, not enough to warn away from alternative reasonable interpretation of law).

[55] Indeed, in the one case DOJ brought invoking OIG guidance regarding suspect JVs, the court barred DOJ from introducing the OIG guidance to support its theory that the JV violated the FCA and AKS. *See McKesson*, 784 F. Supp. 2d at 677, n. 10 ("To the extent the Government seeks to introduce the OIG Special Advisory Bulletin …, the Court deems such evidence as improper" because the document was merely "agency interpretations of regulations" and thus lack "the force of authoritative law" and is "not binding on this Court"). The government ultimately lost the case at trial. *See id.*, 900 F. Supp. 2d 683 (N.D. Miss. 2012).

[56] *See, e.g., SuperValu Inc.*, 9 F.4th at 472; *N.C. Baptist Hosp.*, 818 F. App'x at 182-84, n. 6; *Allergan, Inc.*, 746 F. App'x at 109-10; *McGrath*, 690 F. App'x at 552; *Donegan*, 833 F.3d at 880; *Purcell*, 807 F.3d at 289; *Mayo Found.*, 729 F.3d at 832; *Safeway Inc.*, 466 F. Supp. 3d at 939-41.

[57] *See, e.g., Carlisle HMA*, 2010 U.S. Dist. LEXIS at *32; *Cardiothoracic & Vascular Surgical Assocs.*, 2004 U.S. Dist. LEXIS 29436, at *27; *see also Bingham*, 783 Fed. Appx. at 874; *Hanlester Network*, 51 F.3d at 1401; *McKesson Corp.*, 900 F. Supp. 2d at 698-99; *Consol. Med. Transp.*, 458 F. Supp. 2d at 675-77, 683-84.