

UNITED STATES DISTRICT COURT  
 NORTHERN DISTRICT OF OHIO

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 UNITED STATES OF AMERICA ex rel.  
 DONALD GALE, Relator

Plaintiff,

v.

OMNICARE, INC.,

Defendant.

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CASE NO. 1:10-cv-127

OPINION & ORDER  
 [Resolving Doc. 82.]

JAMES S. GWIN, UNITED STATES DISTRICT JUDGE:

In this *qui tam* action, Relator Donald Gale, on behalf of the United States, says that Defendant Omnicare, Inc. gave nursing homes discounts on Medicare Part A services in exchange for referrals of other patients with government-reimbursable drug costs.<sup>1/</sup> Gale says that these discounts are kickbacks in violation of the Medicare Anti-Kickback Statute<sup>2/</sup> and render the resulting Medicare reimbursements fraudulent.<sup>3/</sup> He sues on behalf of the United States under the False

<sup>1/</sup>[Doc. [1](#) at 8.]

<sup>2/</sup>[42 U.S.C. § 1320a-7b\(a\)\(3\)](#).

<sup>3/</sup>[Doc. [1](#) at 8-10.]

Claims Act.

Gale now moves for partial summary judgment.<sup>4/</sup> He seeks summary judgment for false claims related to one skilled nursing facility, the Montefiore Home (“Montefiore”), as well as summary judgment on several of Omnicare’s affirmative defenses. Omnicare opposes the motion because, it says, genuine issues of material fact exist as to whether the discounted pricing that Omnicare provided Montefiore constituted remuneration within the meaning of the Anti-Kickback Statute and whether Omnicare intended the discounted pricing to induce the referral of other Medicare-reimbursable patients. It also says that summary judgment is inappropriate on three of the challenged affirmative defenses. For reasons that follow, the Court finds that Omnicare offers sufficient evidence to raise a triable issue on the Montefiore contracts. Furthermore, the Court finds that genuine issues of material fact control the validity of two of Omnicare’s affirmative defenses. Accordingly, the Court DENIES Gale’s motion as to the Montefiore contracts and Omnicare’s seventeenth and eighteenth affirmative defenses. The Court GRANTS Gale’s motion as to Omnicare’s sixth affirmative defense—that Gale’s share of any award should be reduced because he has unclean hands—because Omnicare lacks standing to assert this defense.

**I.**

In earlier Opinions and Orders, the Court summarized the allegations of Gale’s complaint. Omnicare supplies prescription drugs to long-term healthcare facilities, including many Medicare-certified Skilled Nursing Facilities (“SNFs”).<sup>5/</sup> Gale worked for Omnicare from 1994 until 2010 as a consulting pharmacist, director, director of operations, vice president of operations, and general

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<sup>4/</sup>[Doc. [82.](#)]

<sup>5/</sup>[Doc. [1](#) at 1, 6.]

manager of its Wadsworth, Ohio, pharmacy.<sup>6/</sup>

Gale's complaint targets Omnicare's practices surrounding Medicare Part A, which provides prescription drug coverage for patients in SNFs. Generally, under Part A, the Government reimburses SNFs a fixed fee per patient, per day for the patient's overall care (a per diem) based on the patient's condition.<sup>7/</sup> In turn, SNFs pay Omnicare a per diem for any prescription drugs or supplies that the patient needs.<sup>8/</sup> Thus, if a SNF can minimize per-diem drug costs for a Part A patient, the Part A reimbursement will give the highest profit.<sup>9/</sup> Gale says that Omnicare offered a number of kickbacks, including discounts and even below-cost per diem pricing, to some SNFs on their Part A patients in return for referrals of other patients that Omnicare could bill against other public insurance programs.<sup>10/</sup> Gale says that these discounts are remuneration in exchange for the referral of customers (the Part D patients) and thus violate the Medicare Anti-Kickback Statute.<sup>11/</sup> He says that all of the Part A reimbursements submitted as a result of this scheme violated the Medicare Anti-Kickback Statute.<sup>12/</sup>

Gale sues under the False Claims Act.<sup>13/</sup> Generally, the False Claims Act says that anyone who makes a fraudulent claim for payment against the Government is liable for a civil penalty plus

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<sup>6/</sup>[Doc. [1](#) at 1.]

<sup>7/</sup>[Doc. [1](#) at 6.]

<sup>8/</sup>[Doc. [1](#) at 6.]

<sup>9/</sup>[Doc. [1](#) at 6.]

<sup>10/</sup>[Doc. [1](#) at 8.]

<sup>11/</sup>[Doc. [1](#) at 9-10.]

<sup>12/</sup>[Doc. [1](#) at 9-10.]

<sup>13/</sup>[31 U.S.C. § 3729](#) *et seq.*

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three times the amount of damages sustained by the Government.<sup>14/</sup> A private party, or relator, may bring a *qui tam* suit on behalf of the Government by filing the complaint under seal, giving the Government an opportunity to prosecute the suit and may prosecute the case themselves if the Government declines to do so.<sup>15/</sup> In exchange for undertaking this effort, the relator becomes entitled to a percentage of any penalty or settlement obtained from the lawsuit.<sup>16/</sup>

On January 19, 2010, Gale filed a sealed complaint as a relator under the False Claims Act and served it on the United States.<sup>17/</sup> He made seven claims.<sup>18/</sup> On April 4, 2011, the United States notified the Court of its intention not to intervene, and the Court unsealed the complaint.<sup>19/</sup> On January 27, 2012, Omnicare moved to dismiss this lawsuit for failure to state a claim upon which relief can be granted under Federal Rules of Civil Procedure 12(b)(6) and 9(b).<sup>20/</sup> On September 26, 2012, the Court granted Omnicare's motion to dismiss counts five, six, and seven, but denied Omnicare's motion to dismiss counts one through four.<sup>21/</sup>

Gale now moves for partial summary judgment. First, Gale seeks summary judgment on liability for false claims related to Omnicare's contracts with Montefiore from January 19, 2004 to

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<sup>14/</sup>[31 U.S.C. § 3729\(a\)\(1\)\(G\).](#)

<sup>15/</sup>[31 U.S.C. § 3730\(b\)-\(d\).](#)

<sup>16/</sup>[31 U.S.C. § 3730](#) *et seq.*

<sup>17/</sup>[Doc. [1.](#)]

<sup>18/</sup>[Doc. [1.](#)]

<sup>19/</sup>[Docs. [8](#), [12.](#)]

<sup>20/</sup>[Doc. [26.](#)]

<sup>21/</sup>[Doc. [36.](#)]

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the filing of his complaint on January 19, 2010.<sup>22/</sup> Second, Gale seeks summary judgment on three of Omnicare’s affirmative defenses.<sup>23/</sup>

On April 9, 2001, Montefiore contracted with NeighborCare, for pharmacy supply services.<sup>24/</sup> Under the terms of the contract Neighborcare billed Montefiore directly for “products or services where [Montefiore] is not eligible to be separately reimbursed for such products and services . . . including . . . residents whose care is covered by Medicare Part A.”<sup>25/</sup> The rate of these reimbursements was subject to negotiation, but correspondence dated August 28, 2003, indicates that this rate was \$22.50 from July 1, 2003 to December 31, 2003.<sup>26/</sup> Correspondence also indicates that NeighborCare would review its costs associated with this arrangement and the parties would make any necessary changes to the rate—a “true up” in industry speak. The same contract also specifies that “[f]or pharmaceutical products and related services provided to residents other than residents for whose care Facility is financially responsible . . . Neighborcare shall bill Facility, the resident, responsible party, or third party payer, as described below at NeighborCare’s usual and

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<sup>22/</sup>With its ruling on Omnicare’s Motion to Dismiss, the Court found that all claims in Relator’s Complaint, which pre-date January 19, 2004, are barred by the FCA’s statute of limitations. [Doc. [36](#) at 9.]

<sup>23/</sup>[Doc. [82](#).] Gale also sought summary judgment on Omnicare’s affirmative defenses 1-4, 7-16, 19, 21-23, and 25. With its opposition to the motion, Omnicare withdraws these defenses, making that portion of Gale’s motion moot. [Doc. [83](#) at 4 n.2.]

<sup>24/</sup>[Doc. [82-9](#).] Omnicare challenges the authenticity of many of Gale’s exhibits, including these contracts, and moves that they be stricken. [Doc. [83](#) at 19 n.6.] Gale disputes the appropriate legal standard, but with his reply, Gale also files a declaration by one of his attorneys authenticating the documents. [Doc. [85](#) at 14 n.10; Doc. [85-8](#).] Construed charitably, Omnicare chastises Gale for not following the formalities of Federal Rule of Evidence 901 and for not submitting an affidavit sufficient to support a finding that these were Omnicare’s documents produced during discovery. The Court does not decide whether the documents might otherwise have been considered, but finds the attorney declaration “sufficient to support a finding that” these documents are what they appear to be. Omnicare, of course, remains free to contest the authenticity of these documents at trial provided that it has a good faith basis to do so.

<sup>25/</sup>[Doc. [82-9](#) at 12.]

<sup>26/</sup>[Doc. [82-9](#) at 17.]

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customary price.”<sup>27/</sup>

In July of 2005, Omnicare acquired NeighborCare.<sup>28/</sup> In November of 2005, Omnicare agreed to a new contract with Montefiore.<sup>29/</sup> Under the terms of the new agreement, Omnicare would charge Montefiore \$21.25 for Medicare Part A per diem patients —less than the \$22.50 specified in the preceding period.<sup>30/</sup> But this agreement also included a page-and-a-half list of drugs excluded from coverage under the per diem pricing.<sup>31/</sup> Again, the agreement also indicates that Omnicare would provide medications for Part D patients at its usual and customary costs, which it would bill directly to Medicare.<sup>32/</sup>

By 2009, internal Omnicare emails show that during 2008, Omnicare continued to bill Montefiore a per diem of \$21.25 for Part A patients, but that the usual and customary charge for those services would have been \$35.97.<sup>33/</sup> Thus, one Omnicare analyst said, “looks like

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<sup>27/</sup>[Doc. [82-9](#) at 13.] According to Omnicare’s Regional Vice President, Rolf Schrader,

[a]s used in Omnicare's pharmacy services agreements, the term “Usual and Customary” (also referred to as “U&C”) refers to a specific pricing formula in a customer's contract, which will vary by customer or contract. For example, in Omnicare’s pharmacy services contract with Montefiore, the “U&C” formula was defined as: AWP- 14.4% + \$3.70 for brand name prescription drugs. That is, the published “AWP” (an industry list price benchmark) for the specific brand name drug, minus 14.4%, plus a \$3.70 dispensing fee.

[Doc. [83-1](#) at 4.] Gale elaborates that this is the fee that Omnicare would charge for these services on a fee for service basis. [Doc. [83-3](#) at 6-7.] Evidence also indicates that Omnicare’s cost of good sold would be a third number—the cost from the supplier minus any discounts and rebates. [Doc. [83-4](#) at 5.]

<sup>28/</sup>[Doc. [83-1](#) at 6.]

<sup>29/</sup>[Doc. [82-11](#) at 30.]

<sup>30/</sup>[Doc. [82-11](#) at 13.]

<sup>31/</sup>[Doc. [82-11](#) at 18-19.] The agreement also excluded HIV/AIDS medications, immunosuppressant medications, and cancer/pain management medications. [Doc. [82-11](#) at 17.]

<sup>32/</sup>[Doc. [82-11](#) at 14-15.]

<sup>33/</sup>[Doc. [82-15](#).]

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[Omnicare's] Per Diem [sic] revenue would increase by 69% moving to [fee for service] (great for the pharmacy, much higher cost for the facility).<sup>34/</sup> Furthermore, Omnicare emails indicate that Omnicare may have known that it was losing money from the Montefiore per diem arrangement.<sup>35/</sup>

Later that year, Omnicare apparently sought to true up per diem arrangements with some skilled nursing facilities, including Montefiore.<sup>36/</sup> On December 10, 2009, Rolf Schrader, an Omnicare Regional Vice President emailed Gale saying “[I] am attaching the [patient per diem] Options. For Montefiore, you can see what it would take to keep the current per diem.”<sup>37/</sup> An attached form letter explained that the new contract would have to exclude more high-cost drugs and over-the-counter products and instead bill these items on a fee for service basis.<sup>38/</sup> The negotiations apparently continued. On June 17, 2010, Schrader wrote to Montefiore’s Chief Financial Officer proposing a schedule of cost increases in the per diem rates to reach “an interim target per diem rate of \$26.00.”<sup>39/</sup> On July 29, 2010, and apparently in response to Schrader’s letter, Montefiore notified Omnicare of its intention to terminate the pharmacy services agreement effective October 1, 2010.<sup>40/</sup>

Gale now moves for summary judgment. He says that Omnicare knew that it was charging below cost for the Montefiore per diems patients, and did so to induce Montefiore to refer its other

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<sup>34/</sup>[Doc. [82-15](#).]

<sup>35/</sup>[Doc. [82-25](#).] In subsequent deposition testimony, Omnicare’s corporate representative said that it could not say whether the Part A component of Montefiore’s business was ever profitable. [Doc. [85-3](#) at 17.]

<sup>36/</sup>[Doc. [82-16](#).]

<sup>37/</sup>[Doc. [82-16](#) at 1.]

<sup>38/</sup>[Doc. [82-9](#) at 17.]

<sup>39/</sup>[Doc. [101-2](#) at 1.]

<sup>40/</sup>[Doc. [97-7](#) at 3.]

patients, including Part D patients, because Medicare would pay for those patients at the usual and customary price. Omnicare responds that there is no evidence that Omnicare intended the per diem arrangement to induce referrals of other patients. That is, Omnicare says that there was no *quid pro quo*—no Part A discount, no other patients. Omnicare also says that Gale fails to establish fair market value for the Part A services Gale says that Omnicare discounted.

Gale also moves for summary judgment on Omnicare’s seventeenth and eighteenth affirmative defenses. The seventeenth and eighteenth affirmative claim compliance with statutory and regulatory safe harbors contained in 42 U.S.C. § 1320a-7b(b)(3) and 42 C.F.R. § 1001.952.<sup>41/</sup> Omnicare says that these issues are tied up with the merits, and, thus, summary judgment is likewise inappropriate on these defenses.

Finally, Gale moves for summary judgment on Omnicare’s sixth affirmative defense. The sixth affirmative defense says that “Gale’s claims are barred, in whole or in part, by the doctrines of unclean hands, inequitable conduct, and/or *in pari delicto*.”<sup>42/</sup> Omnicare says that this defense tracks 31 U.S.C. § 3730(d)(3), which provides that “if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive.” Gale says that Omnicare lacks standing to interpose this defense.

## II.

### A. Summary Judgment

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<sup>41/</sup>[Doc. [42](#) at 47-48.]

<sup>42/</sup>[Doc. [42](#) at 46.]



Summary judgment is proper “if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.”<sup>43/</sup> The moving party, Relator Gale, has the initial burden of showing the absence of a genuine issue of material fact as to an essential element of the Gale’s case.<sup>44/</sup> “A fact is material if its resolution will affect the outcome of the lawsuit.”<sup>45/</sup> The movant meets its burden by “informing the district court of the basis for its motion, and identifying those portions of ‘the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,’ which it believes demonstrate the absence of a genuine issue of material fact.”<sup>46/</sup>

Once the Relator satisfies this burden, the burden shifts to Omnicare to set forth specific facts showing a triable issue.<sup>47/</sup> It is not sufficient for Omnicare to show that there is some existence of doubt as to the material facts.<sup>48/</sup> Nor can Omnicare rely upon mere allegations or denials of its pleadings.<sup>49/</sup> In responding to a summary judgment motion, Omnicare “cannot rely on the hope that the trier of fact will disbelieve the movant’s denial of a disputed fact, but must present affirmative evidence in order to defeat a properly supported motion for summary judgment.”<sup>50/</sup>

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<sup>43/</sup>[\*Daugherty v. Sajar Plastics, Inc.\*, 544 F.3d 696, 702 \(6th Cir. 2008\).](#)

<sup>44/</sup>[See \*Celotex Corp. v. Catrett\*, 477 U.S. 317, 323 \(1986\).](#)

<sup>45/</sup>[\*Martingale, LLC v. City of Louisville\*, 361 F.3d 297, 301 \(6th Cir. 2004\).](#)

<sup>46/</sup>[See \*Celotex Corp.\*, 477 U.S. at 323 \(quoting \*Fed. R. Civ. P. 56\(c\)\*\).](#)

<sup>47/</sup>[See \*Matsushita Elec. Indus. Co. v. Zenith Radio Corp.\*, 475 U.S. 574, 587 \(1986\).](#)

<sup>48/</sup>[See \*id.\*](#) at 586.

<sup>49/</sup>[Fed. R. Civ. P. 56\(e\).](#)

<sup>50/</sup>[See \*Street v. J.C. Bradford & Co.\*, 886 F.2d 1472, 1477 \(6th Cir. 1989\)](#) (internal quotation omitted).

In deciding a motion for summary judgment, the Court views the factual evidence and draws all reasonable inferences in favor of the non-moving party.<sup>51/</sup> “The disputed issue does not have to be resolved conclusively in favor of the non-moving party, but that party is required to present some significant probative evidence that makes it necessary to resolve the parties’ differing versions of the dispute at trial.”<sup>52/</sup> Ultimately the Court must decide “whether the evidence presents sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.”<sup>53/</sup>

#### **B. The False Claims Act and the Medicare Anti-Kickback Statute**

The Medicare Anti-Kickback Statute (“AKS”) prohibits

knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--

- (A) 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, or
- (B) to purchase, lease, order, or arrange for or recommend 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.<sup>54/</sup>

Accordingly, to violate the AKS, 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. As applied to this case, Gale

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<sup>51/</sup>[Thomas v. Cohen, 453 F.3d 657, 660 \(6th Cir. 2004\)](#) (citations omitted).

<sup>52/</sup>[60 Ivy Street Corp. v. Alexander, 822 F.2d 1432, 1435 \(6th Cir. 1987\)](#) (citing [First Nat’l Bank of Ariz. v. Cities Serv. Co., 391 U.S. 253, 288-89 \(1968\)](#)).

<sup>53/</sup>[Martingale, 361 F.3d at 301.](#)

<sup>54/</sup>[42 U.S.C. § 1320a-7b\(b\)\(2\).](#)

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must show that Omnicare knowingly gave some remuneration to induce Montefiore to refer Medicare patients.

Generally, remuneration means “payment” or “compensation.”<sup>55/</sup> But, importantly, 42 C.F.R. § 1001.952(h) provides an extensive list of exemptions to “remuneration” under the AKS. Relevant here, “‘remuneration’ does not include a discount, as defined in paragraph (h)(5).”<sup>56/</sup> Paragraph (h)(5), in turn, specifies exemptions from the discount safe harbor, *i.e.* exceptions to the safe harbor exception:

the term discount means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction. The term discount does not include--

...

(ii) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;

...

(vii) Other remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section.

Thus, to prove that it did not pay remuneration, Omnicare may show *inter alia*, either that its pricing was that of an arms-length transaction *or* that the discount it was not intended to induce a referral.<sup>57/</sup>

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<sup>55/</sup>[REMUNERATION, Black's Law Dictionary \(9th ed. 2009\).](#)

<sup>56/</sup>[42 C.F.R. § 1001.952\(h\).](#)

<sup>57/</sup>As one court explained the burdens involved:

Once the United States has demonstrated proof of each element of a violation of the Anti-Kickback . . . Statutes, the burden shifts to the defendant to establish that his conduct was protected by a safe harbor or exception; the United States need not prove, as an element of its case, that defendant's conduct does not fit within a safe harbor or exception.

[United States v. Rogan, 459 F. Supp. 2d 692, 716 \(N.D. Ill. 2006\) aff'd, 517 F.3d 449 \(7th Cir. 2008\)](#) (citing [United](#)

In turn, the False Claims Act (“FCA”) provides that

any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . . is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. § 2461 note; Public Law 10[1]-4101), plus 3 times the amount of damages which the Government sustains because of the act of that person.<sup>58/</sup>

In this context, “the terms ‘knowing’ and ‘knowingly’—(A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud.”<sup>59/</sup>

Compliance with the AKS is a material term of Medicare reimbursement.<sup>60/</sup> Thus, to succeed here, Gale must show that Omnicare violated the AKS, and that it knew it was in violation of the AKS when it presented or caused SNFs to present Medicare claims for reimbursement.

### III.

The definitions of the AKS as interpreted by 42 C.F.R. § 1001.952(h) are somewhat circular: “Remuneration” does not include a discount” but “[t]he term discount does not include . . . [s]upplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service.” That is, remuneration can mean “[s]upplying one good or service . . . at a reduced charge to induce the purchase of another good or service.” And the AKS prohibits “offering or paying any remuneration to induce another person to refer an individual to a person for

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[States v. Shaw, 106 F.Supp.2d 103, 122 \(D. Mass.2000\)](#)).

<sup>58/</sup>[31 U.S.C. § 3729\(a\)\(1\)\(A\)](#).

<sup>59/</sup>[31 U.S.C. § 3729\(b\)\(1\)](#).

<sup>60/</sup>See [42 U.S.C. § 1320a-7b](#).

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.”<sup>61/</sup> Thus, the concept of inducement is central both to the definition of remuneration and an element of the AKS.

For the sake of clarity, the Court first considers evidence that Omnicare offered a “reduced charge” so as to constitute remuneration and then considers whether that reduced charge was to “induce the purchase of another good or service”<sup>62/</sup> or, in other words “to refer an individual to [Omnicare] 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.”<sup>63/</sup> As these questions are central both to Omnicare’s seventeenth and eighteenth affirmative defenses as well as to summary judgment on the Montefiore contract, the Court considers them together.

#### **A. Reduction**

Omnicare presents sufficient evidence to raise a triable issue as to whether it offered Montefiore price reductions that qualify as remuneration within the meaning of the AKS. As an initial matter, the parties dispute the relevant baseline to evaluate whether Omnicare offered reductions within the meaning of the regulation. Omnicare says that the baseline should be “fair market value.”<sup>64/</sup> Gale says that the baseline is Omnicare’s own usual and customary rate.<sup>65/</sup>

There are problems with either definition, but Omnicare’s more closely approximates the

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<sup>61/</sup>[42 U.S.C. § 1320a-7b\(b\)\(2\)](#).

<sup>62/</sup>[42 C.F.R. § 1001.952\(h\)](#).

<sup>63/</sup>[42 U.S.C. § 1320a-7b\(b\)\(2\)](#).

<sup>64/</sup>[Doc. [83](#) at 15.]

<sup>65/</sup>[Doc. [82-1](#) at 11.]

statute's intent.<sup>66/</sup> Filling the statutory gap, 42 C.F.R. § 1001.952(h)(5) separates the discount safe harbor from illegal remuneration: "the term discount means a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction. The term discount does not include . . . [s]upplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service." In essence, remuneration, in context of the allegations of this case and the affirmative defenses that Omnicare asserts, is a reduction in the Part A per diem price that Omnicare charges Montefiore as compared to the price it would have charged Montefiore for the same services absent the rest of Montefiore's contract—including Part D patient referrals.<sup>67/</sup>

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<sup>66/</sup>Under Omnicare's proposed standard, Gale would have to show that Omnicare's prices were below what Montefiore could obtain from other companies. The problem with this construction is that if the industry were permeated with these swapping practices, then all companies might be engaging in kickbacks. Indeed, nothing in Omnicare's proposed definition would prevent a pharmacy from doing anything short of servicing Part A patients for free in exchange for referrals so long as the practice was common in the industry. Surely, this definition strays too far from the common meaning of remuneration and lacks any authority in the statute.

Likewise, Relator's proposed reliance on Omnicare's own Usual and Customary price could likewise create bizarre results. Evidence suggests that

[a]s used in Omnicare's pharmacy services agreements, the term "Usual and Customary" (also referred to as "U&C") refers to a specific pricing formula in a customer's contract, which will vary by customer or contract. For example, in Omnicare's pharmacy services contract with Montefiore, the "U&C" formula was defined as: AWP- 14.4% + \$3.70 for brand name prescription drugs. That is, the published "AWP" (an industry list price benchmark) for the specific brand name drug, minus 14.4%, plus a \$3.70 dispensing fee.

[Doc. [83-1](#) at 4.] This appears to be roughly the fee that Omnicare would charge for these services on a fee for service basis. Yet this definition also lacks any authority in the statute, and Gale also fails to identify a single case in which a court has granted legal status to such a definition. Further, Gale's definition of remuneration, "anything of value in any form," might sweep in any contract rendering the definition operatively meaningless.

<sup>67/</sup>This approach is largely consistent with other courts' consideration of this issue. See [United States v. Bay State Ambulance and Hosp. Rental Serv., Inc.](#), 874 F.2d 20, 29-31 (1st Cir. 1989) (finding that "trial court did not err in not specifically instructing the jury that the government had to prove that the payments received were not reasonable for the actual work done. The gravamen of Medicare Fraud is inducement. Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient."); [United States v. Greber](#), 760 F.2d 68, 72 (3d Cir. 1985) (holding that "[i]f the payments were intended to induce the physician to use Cardio-Med's services, the statute was violated, even if the payments were also intended to compensate for professional services"); [U.S. ex rel. Jamison v. McKesson Corp.](#), 900 F. Supp. 2d 683, 698 (N.D. Miss. 2012) ("Indeed, the evidence showed that the Government's allegations that CSMS 'dangled' the general medical supply contract or 'carved out' enteral supply for MediNet or McKesson to be without merit, and failed to prove that MediNet offered its services below fair market value, below actual costs, or at a discount. Therefore, there was no inducement or remuneration necessary for an AKS violation."); [Shaw](#), 106 F. Supp. 2d at 117-18 ("In sum, for the purposes of

In other words, if Omnicare charges the same price for Part A services regardless of whether Montefiore refers the Part D patients, then Omnicare has not given anything of value in exchange for the Part D patient referrals.<sup>68/</sup> It is not simply what others in the industry would have charged for the same services—which could reflect widespread kickback practices in the industry—but *fair* market value, the price at which an arm’s-length market transaction would value these services.<sup>69/</sup>

Under this definition, Omnicare’s Usual and Customary price would be evidence of the fair market value, but so would the prices charged by Omnicare’s competitors. Omnicare’s costs would also bear on remuneration because no rational market participant would intentionally lose money on its Part A patients unless otherwise compensated. And, so, the real question in this case will be whether any payments were made with the intent of inducement. But, first, the Court considers the record with regard to remuneration.

Gale presents evidence that Omnicare continually lost money on its Part A business with Montefiore. He compares Omnicare’s net revenue from Montefiore’s Part A patients to Omnicare’s “invoice cost” and shows that over the relevant period, per diem invoice costs continually outpaced

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interpreting the ‘discount exception’ (paragraph (A) of § 1320a–7b(b)(3) of the anti-kickback statute, as opposed to paragraph (E), the safe-harbor regulations), a rebate is a kind of discount, as well as a kind of reduction in price. Both can be a form of remuneration that if offered or received with the requisite *mens rea*, might be considered ‘illegal remuneration’ under the statute, and thus cannot be barred entirely from consideration under the ‘discount exception.’”). And, indeed, as Gale argues, remuneration could be “anything of value in any form whatsoever”; it need not be cash or even price reductions. [United States v. The Health Alliance of Greater Cincinnati, No. 1:03-CV-00167, 2008 WL 5282139 \(S.D. Ohio Dec. 18, 2008\)](#) (quoting [OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 \(1991\)](#)).

<sup>68/</sup>See [Klaczak v. Consol. Med. Transp., 458 F. Supp. 2d 622, 626 \(N.D. Ill. 2006\)](#) (“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.”).

<sup>69/</sup>Cf. [U.S. ex rel. Obert-Hong v. Advocate Health Care, 211 F. Supp. 2d 1045, 1049 \(N.D. Ill. 2002\)](#) (“We note that fair market value here may differ from traditional economic valuation formulae. Normally, we would expect the acquisition price to account for potential revenues from future referrals. Because the Anti-Kickback Act prohibits any inducement for those referrals, however, they must be excluded from any calculation of fair value here. See [42 C.F.R. 1001.952\(b\) and \(c\)](#). There is, nonetheless, some value that would be considered fair and would comply with the statute.”).

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revenues.<sup>70/</sup> Further, Gale submits an email that he received from Michael Mautz on August 8, 2008, in which Mautz, an Omnicare financial analyst, says that Omnicare’s “current \$21.25 Per Diem [for Montefiore] is showing negative [gross margin].”<sup>71/</sup> Nonetheless, Omnicare shows evidence that its invoice cost is not its true net cost because it does not include discounts that Omnicare obtained from its suppliers.<sup>72/</sup> While this testimony would seem in tension with Mautz’s analysis, a jury could believe either story, and summary judgment is not appropriate.

Likewise, while the June 17, 2010, letter from Rolf Schrader, Omnicare’s Regional Vice President to Montefiore’s Chief Financial Officer Mark H. Weiss is evidence that Omnicare paid remuneration to Montefiore to obtain the Part D work, it does not compel summary judgment for Gale. The letter says, “[Montefiore’s] current per diem rate for Omnicare’s services does not satisfy the standards for ‘fair market value’ under federal law.”<sup>73/</sup> While Schrader’s legal conclusions are hardly binding on this Court, they certainly would allow a jury to infer that Omnicare was charging less than market rates and knew that it was doing so.<sup>74/</sup> Nonetheless, Omnicare creates a triable issue by sending Montefiore’s reply: Montefiore responded that it “d[id] not agree with Omnicare’s position regarding an increase in the per diem rate the products and services being provided under the Pharmacy Agreement.”<sup>75/</sup> Further, Montefiore said that it would seek a new pharmacy at the

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<sup>70/</sup>[Doc. [82-8](#).]

<sup>71/</sup>[Doc. [82-23](#).]

<sup>72/</sup>[Docs. [83-1](#) at 6; [85-3](#) at 14-15.]

<sup>73/</sup>[Doc. [101-2](#) at 2.]

<sup>74/</sup>Letters that Gale submits concerning Omnicare’s arrangements with the Menorah Park [Docs. [101-3](#), [101-4](#)] are of little probative value to the Montefiore contract. Gale presents no evidence to suggest that the facilities are comparable.

<sup>75/</sup>[Doc. [97-7](#) at 3.]



conclusion of its existing agreement with Omnicare<sup>76/</sup>—suggesting that it believed that it could find a better deal on the market. Thus, while a jury could conclude that Omnicare was ~~paying~~ charging below market value to Montefiore, it could also conclude that Omnicare engaged in hard bargaining by misstating the law.

## **B. Inducement**

Likewise, Omnicare raises a triable issue as to whether it gave Part A reductions to induce the referral of other Medicare-reimbursable patients. At the heart of Gale’s case, he must show that Omnicare “willfully offer[ed] or pa[aid] any remuneration . . . to induce [Montefiore] . . . to refer an individual to [Omnicare] 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.” That is, he has to show that there was intent: Omnicare gives Montefiore a discount on Part A, and, in return Montefiore refers other patients. Since the servicing of all of these patients is rolled into the same contract, and since that contract does not include direct evidence of remuneration for referrals, a jury would need to infer that Omnicare intended to use remuneration to induce referrals from indirect evidence. Thus, at summary judgment, the Court evaluates whether there is sufficient evidence for a jury not to infer intent to remunerate in exchange for patient referrals. There is.

Statements by Gale himself indicate that any reduced pricing on Omnicare’s Part A arrangement with Montefiore may have been corporate mismanagement rather than an effort to induce referrals. On a chain of emails, Nate Kurash, a Director of Customer Relations at Omnicare asked Relator Gale to give him the revenue numbers for the Montefiore Home.<sup>77/</sup> In response, Gale

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<sup>76/</sup>[Doc. [97-7](#) at 3.]

<sup>77/</sup>[Doc. [82-25](#) at 2-3.]

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asked Mike Mautz, a financial analyst to run the numbers.<sup>78/</sup> Mautz wrote to Gale “See attached file for Montefiore which lists annual Net Sales at \$2.3 million and Gross Margin at \$326,000. Their current \$21.25 Per Diem is showing negative GM.”<sup>79/</sup> Gale wrote back “Is the per diem wrong? How can we have a per diem that is losing us money?”<sup>80/</sup> Gale’s email suggests that any losses stemming from the Montefiore contract may have been the result of corporate mismanagement and failed oversight, not an intent to induce referrals. Other emails within Omnicare suggesting the need to raise the Montefiore per diem also, by one reading, support this interpretation.<sup>81/</sup>

Nonetheless, Omnicare knew that, across the board, its Part A business was not a profit center. Robert Dries, an Omnicare internal auditor and a Rule 30(b)(6) deponent, explained why Omnicare links Part A and Part D reimbursements in the same supply contracts.

Q. Okay. So why would Omnicare -- if a nursing home came to Omnicare and said, “Hey, I would like to get a \$21 per day per diem charge rate for my Part A patients, but I use somebody else for everything else. We would like your reaction to that.” Why wouldn’t Omnicare take that business?

...

A. We wouldn't take the business because it wouldn't be the right thing to do for the patient or the facility.

Q. Why?

A. Because the patient on a Medicare A stay will only be on their Medicare A stay for a few days and then we’ll move to their other benefit. And if we were not servicing then, we wouldn’t be able to charge the other benefit.<sup>82/</sup>

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<sup>78/</sup>[Doc. [82-25](#) at 2.]

<sup>79/</sup>[Doc. [82-25](#) at 1.]

<sup>80/</sup>[Doc. [82-25](#) at 1.]

<sup>81/</sup>[Docs. [82-15](#), [82-16](#), [82-20](#).]

<sup>82/</sup>[Doc. [85-3](#) at 8.]

This testimony suggests that linking Part A and Part D was by design. But it does not necessarily imply that this was the arrangement at the Montefiore home, nor that Omnicare did not simply have a policy of taking Part A and Part D—all or nothing—without remuneration—something of value beyond what some hypothetical company may have charged to provide these services individually. Thus, at trial, a jury will have to determine whether Omnicare intended below-market pricing on the Part A per diems to induce Montefiore to refer Part D patients, or whether this pricing was merely the product of sloppy accounting and management at Omnicare.

Because disputes of material fact exist as to whether any Omnicare offered Montefiore below-fair-market-value pricing on Part A patients in exchange for Part D patients, the Court denies Gale’s motion for summary judgment on the Montefiore contract and on Omnicare’s seventeenth and eighteenth affirmative defenses.

#### IV.

Finally, the Court grants Gale’s motion for summary judgment on Omnicare’s Sixth affirmative defense. With its sixth affirmative defense, Omnicare says that “Gale’s claims are barred, in whole or in part, by the doctrines of unclean hands, inequitable conduct, and/or *in pari delicto*.”<sup>83/</sup> Omnicare says that this defense “tracks 31 U.S.C. § 3730(d)(3),”<sup>84/</sup> which provides that “if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive.” Responding to this argument, Gale says that Omnicare lacks standing to assert

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<sup>83/</sup>[Doc. [42](#) at 46.]

<sup>84/</sup>[Doc. [83](#) at 24.]

this defense.<sup>85/</sup>

The False Claims Act envisions a separate proceeding, after judgment or settlement, to determine the relator's share of any recovery.<sup>86/</sup> “[T]he Relators’-Share Litigation d[oes] not directly involve the *qui tam* defendants. . . . [Defendants] ha[ve] no legal standing or right to participate in the proceedings”<sup>87/</sup> Should Gale make any recovery, the United States would have standing to assert that Gale’s share of the award should be reduced. But this would be a matter between Gale and the United States. It would not concern Omnicare, although Omnicare would, of course, be free to assist the government. Accordingly, the Court grants Gale’s motion for summary judgment as to this defense as asserted by Omnicare.

V.

For these reasons, the Court DENIES Gale’s motion for summary judgment as to the Montefiore contract and Omnicare’s seventeenth and eighteenth affirmative defenses. The Court

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<sup>85/</sup>[Doc. [85](#) at 20.]

<sup>86/</sup>See [U.S. ex rel. Taxpayers Against Fraud v. Gen. Elec. Co.](#), 41 F.3d 1032, 1036 (6th Cir. 1994); see also [Roberts v. Accenture, LLP](#), 707 F.3d 1011, 1017-18 (8th Cir. 2013) (“In contrast, section 3730(d) only comes into play at the conclusion of a case, after the action has already proceeded to a judgment or a settlement.”) see also e.g. [U.S. ex rel. Schroeder v. CH2M Hill](#), CV-09-5038-LRS, 2013 WL 1982330 (E.D. Wash. May 13, 2013).

<sup>87/</sup>[Taxpayers Against Fraud](#), 41 F.3d at 1046; see also [U.S. ex rel. Vainer v. DaVita, Inc.](#), 1:07-CV-2509-CAP, 2013 WL 1342431 (N.D. Ga. Feb. 13, 2013) (“Such an offset is allowed only pursuant to a claim under 31 U.S.C. § 3730(d)(3) whereby the United States government can offset its recovery from a liable defendant by the amount of the *qui tam* plaintiff’s own unclean hands.”).

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GRANTS Gale's motion for summary judgment on Omnicare's sixth affirmative defense.

IT IS SO ORDERED.

Dated: July 23, 2013

s/ James S. Gwin  
JAMES S. GWIN  
UNITED STATES DISTRICT JUDGE