

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

THE UNITED STATES OF AMERICA
ex rel. DONALD GALE

Plaintiff,

v.

OMNICARE, INC.,

Defendant.

CASE NO. 1:10-CV-00127

OPINION & ORDER
[Resolving Doc. [117](#)]

JAMES S. GWIN, UNITED STATES DISTRICT JUDGE:

In this *qui tam* action, Relator David Gale, on behalf of the United States, says that Defendant Omnicare, Inc., gave skilled nursing facilities illegal discounts on Medicare Part A services in exchange for referrals of other patients with government-reimbursable drug costs.^{1/} Gale says that these discounts are kickbacks that violate the Medicare Anti-Kickback Statute^{2/} and make Medicare reimbursements fraudulent.^{3/} He sues on behalf of the United States under the False Claims Act.

Omnicare moves to exclude trial evidence regarding amounts paid by Medicare Part D carriers or Medicaid agencies.^{4/} For the reasons that follow, the Court **DENIES** Defendant Omnicare’s motion in limine and **DENIES** Omnicare leave to assert a defense based on a previous settlement agreement with the United States.

^{1/}Doc. [1](#) at ¶¶ 24-25.

^{2/}[42 U.S.C. § 1320a-7b\(a\)\(3\)](#).

^{3/}Doc. [1](#) at ¶ 5.

^{4/}Doc. [117](#).

I. Factual and Procedural Background

In several earlier Opinions and Orders, the Court summarized Gale’s complaint.^{5/} Defendant Omnicare supplies prescription drugs to long-term healthcare facilities, including many Medicare-certified Skilled Nursing Facilities (“SNFs”).^{6/} Relator Gale worked for Omnicare from 1994 until 2010 as a consulting pharmacist, director, director of operations, vice president of operations, and general manager of its Wadsworth, Ohio, pharmacy.^{7/}

Gale’s complaint targets Omnicare’s practices with Medicare Part A drug coverage for patients in SNFs. He says that Omnicare offered kickbacks, including discounts and even below-cost per-diem Medicare Part A pricing.^{8/} Because Medicare pays the SNFs at a fixed per-diem rate, Omnicare’s lower per-diem medication rate increases the SNFs profits.^{9/} Relator Gale says that Omnicare used these below-cost per-diem rates to obtain SNF referrals of other Medicare customers, especially Part D customers.^{10/} Gale says this arrangement violates the Medicare Anti-Kickback Statute and has sued under the False Claims Act on behalf of the United States.^{11/}

Gale said in his complaint that he sought to recover damages “by reason of material false records or statements and false or fraudulent claims for payment or approval, knowingly presented or caused to be presented by Defendant Omnicare, to the Government.”^{12/} Gale also said that the “reduced Medicare Part A per diem rates” “induce[d] the referral of business for which payment

^{5/}See, e.g., Docs. [104](#), [120](#).

^{6/}Doc. [1](#) at ¶¶ 2, 17-18.

^{7/}*Id.* at ¶ 1.

^{8/}*Id.* at ¶ 24.

^{9/}*Id.* at ¶¶ 17-18.

^{10/}*Id.* at ¶ 24.

^{11/}*Id.* at ¶¶ 26-32, 55-62.

^{12/}*Id.* at ¶ 5.

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otherwise may have been made by *other* Federal health care programs.”^{13/} However, Gale also specifically referred to “claims for reimbursement that Defendant Omnicare has submitted or caused to be submitted to Medicare Part A” and said that “Omnicare knew, or was grossly negligent and/or reckless in not knowing, that Medicare Part A would not pay the claims resulting from the practices described herein . . . if it knew that the claims were premised upon kickbacks.”^{14/}

Before this litigation, Omnicare and the United States previously settled a False Claims Act case filed by a different relator.^{15/} In that case, the relator said that Omnicare paid kickbacks to SNFs in the form of below-cost consultant pharmacist services to induce the SNFs to use Omnicare’s dispensing pharmacist services and to have their patients purchase drugs from Omnicare.^{16/} In the settlement agreement, Omnicare agreed to pay \$98 million, and the United States agreed to release Omnicare, but only for that conduct.^{17/} The settlement agreement did not cover “[a]ny liability to the United States . . . for any conduct other than” the conduct that served as a basis for the relator’s lawsuit.^{18/}

This Court has scheduled the case for trial on October 21, 2013.^{19/} On September 13, 2013, Omnicare moved to exclude all evidence of Medicare Part D and Medicaid reimbursements.^{20/} Defendant says that Gale did not plead damages based on Medicare Part D and Medicaid or provide

^{13/}*Id.* at 56, 58 (emphasis added).

^{14/}*E.g., id.* at ¶¶ 27, 31.

^{15/}Doc. [117-8](#).

^{16/}*Id.* at 4-5; Doc. 121 at 3.

^{17/}Doc. [117-8](#) at 6-9.

^{18/}*Id.* at 10.

^{19/}Doc. [50](#) at 4.

^{20/}Doc. [117](#).

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disclosure that he would pursue those damages.^{21/} Omnicare also says its prior settlement with the United States should bar Gale from recovering damages for Medicare Part D and Medicaid reimbursements between September 1, 2005, and September 1, 2008.^{22/} In the alternative, Omnicare says it should be allowed to set-off the money it paid as a part of the prior settlement against any award Gale wins.^{23/}

The Court ordered Gale to respond by September 24, 2013. With his response, Gale says that his complaint and the prior proceedings in this case should have made clear to Omnicare that Gale was seeking all damages arising from any kickbacks, not just Medicare Part A damages.^{24/} Gale also says that the prior settlement agreement did not release Omnicare from the claims that Gale asserts and his claims are not barred by res judicata.^{25/} Gale also says Omnicare has waived any defense based on the settlement by delaying in asserting it.^{26/}

On September 23, 2013, the United States also filed a notice concerning Omnicare's assertion of res judicata.^{27/} The United States says that its prior settlement with Omnicare did not release the claims that Gale is pursuing and that res judicata does not bar him from pursuing those claims.^{28/}

These issues are now ripe.

II. Available Damages

Omnicare has had sufficient notice that Gale will pursue Medicare Part D and Medicaid

^{21/}Doc. [117-1](#) at 3-6.

^{22/}*Id.* at 6-15.

^{23/}*Id.* at 10-11 n.2.

^{24/}Doc. [122](#) at 2-7.

^{25/}*Id.* at 7-13.

^{26/}*Id.* at 7-8, 12-13.

^{27/}Doc. [121](#).

^{28/}*Id.*

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claims as damages for the alleged kickbacks. Additionally, Omnicare's previous settlement with the government does not bar Gale from bringing the present claims. Separately, Omnicare waived any defense based on the previous settlement agreement.

A. Sufficiency of Notice

[Federal Rule of Civil Procedure 54\(c\)](#) states that “[e]very other final judgment [other than a default judgment] should grant the relief to which each party is entitled, even if the party has not demanded that relief in its pleadings.”^{29/} “This rule affords district courts flexibility in crafting relief so that a plaintiff may recover on a valid claim, regardless of counsel’s pleading errors.”^{30/} “[A] plaintiff may obtain relief on an unpleaded theory of recovery only if he proves that theory, he bases it on the wrongful act alleged in the complaint, and the defendant receives fair notice of the theory.”^{31/} In this case, Gale did not specifically state that he was pursuing damages based on Medicare Part D and Medicaid reimbursements. However, he may seek these damages if he can show that Medicare Part D and Medicaid damages are based on the wrongful conduct set out in the complaint and that Omnicare had notice that he would pursue these damages.

Here, Gale says that Omnicare violates the Anti-Kickback Statute by offering below-cost Medicare Part A per diems to SNFs to induce the SNFs to refer their other government-insured

^{29/}[Fed. R. Civ. P. 54\(c\)](#).

Omnicare’s citation to [Boggs v. 3M Co., No. 12-6062, 2013 WL 2378558, \(6th Cir. May 31, 2013\)](#) fails because in *Boggs*, the plaintiff was trying to claim that a new *cause of action* was fairly encompassed within his prior complaint. *Id.* at *2 (“Boggs says his complaint included a *claim for lung cancer* because it referenced ‘silica related occupational lung disease.’”). Here, Gale does not assert a new cause of action. He claims a certain type of damages that he would be able to recover should he win this case and that he did not specifically designate in the complaint.

^{30/}[Yoder v. Univ. of Louisville, 417 F. App’x 529, 530 \(6th Cir. 2011\)](#) (citing [Colonial Refrigerated Transp., Inc. v. Worsham, 705 F.2d 821, 825 \(6th Cir. 1983\)](#)).

^{31/}*Id.*

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patients to Omnicare for their drug needs.^{32/} Gale also says that “a federally funded [healthcare] program . . . would not pay a claim, or would not pay at the rate submitted, if it knew the claim to be based upon an illegal kickback.”^{33/} Although the Sixth Circuit has not ruled on this issue, most courts find the Anti-Kickback Statute makes all claims made after a kickback a false claim because the claimant impliedly (but falsely) certifies that it has complied with all relevant law.^{34/} Accordingly, Gale’s claim for Medicare Part D and Medicaid damages is sufficiently based on the wrongful conduct described in Gale’s complaint.

Omnicare also had notice that Gale would pursue these damages. First, Gale’s complaint says that Omnicare offered the alleged Medicare Part A per-diem kickbacks in order to induce the referral of “the furnishing or the arranging for the furnishing of drugs to *the balance* of the SNFs’ patients.”^{35/} In other words, Gale says that Omnicare offered the alleged kickbacks to get referrals for those patients *not* on Medicare Part A. Gale reiterates this later in his complaint when he says that the kickbacks “induce[d] the referral of business fo which payment otherwise may have been made by *other* Federal health care programs.”^{36/}

In Gale’s motion for partial summary judgment, he quoted the deposition of Omnicare’s corporate designee: “Omnicare ‘not only expects, but it is a fact that Omnicare is the sole provider

^{32/}Doc. 1 at ¶ 24.

^{33/}*Id.* at ¶ 15.

^{34/}[*United States v. Rogan*, 517 F.3d 449, 453 \(7th Cir. 2008\)](#) (“The government offers a subsidy (from the patients’ perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due.”); [*United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 \(5th Cir. 1997\)](#) (“[W]here the government has conditioned payment of a claim upon a claimant’s certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation.”); [*United States ex rel. Pogue v. Diabetes Treatment Ctrs. Of Am., Inc.*, 238 F. Supp. 2d 258, 264 \(D.D.C. 2002\)](#) (“implied false certification of compliance with Anti-Kickback and Stark laws [is] sufficient to state a claim under the False Claims Act”); Doc. 104 at 12 (“Compliance with the [Anti-Kickback Statute] is a material term of Medicare reimbursement.”).

^{35/}Doc. 1 at ¶ 24 (emphasis added).

^{36/}*Id.* at ¶¶ 56, 58 (emphasis added).

in the vast majority of circumstances of . . . *all other payors including government payors such as Part D.*^{37/} And although Gale said that “actual damages” are not an element of a False Claims Act case, Gale stated the revenues from Medicare Part D at the Montefiore facilities as actual damages.^{38/} This Court also has frequently explained in its orders that Gale says that Omnicare engaged in illegal kickbacks “in exchange for the referral of customers (the Part D patients).”^{39/}

Omnicare appears to have been aware of Gale’s focus on Medicare Part D. Dr. Mohan Rao, Omnicare’s designated expert in this case, discusses the relationship between Medicare Part A per-diem rates and annual Part D reimbursements at SNFs in his rebuttal report.^{40/}

Omnicare’s cited cases do not help it.^{41/} Those courts prohibited plaintiffs from asserting new damages because the plaintiff had not disclosed its methods or data to calculate its damages and the lack of opportunity to conduct discovery on the damages claim.^{42/} In this case, Gale has been clear that he seeks Medicare Part D and Medicaid damages and the way to calculate those damages has always been in Omnicare’s possession. Gale had no documents to disclose in his initial disclosures or to produce about his damages until Omnicare provided the figures necessary to determine which SNFs he believes received kickbacks and the Medicare Part D and Medicaid claims Omnicare made

^{37/}Doc. [82-1](#) at 6 (emphasis added).

^{38/}*Id.* at 14.

^{39/}*E.g.*, Doc. [104](#) at 3.

^{40/}Rao Rebuttal Rep. at ¶¶ 8-9, 8-9 (“If Omnicare’s per diem pricing were indeed intended as a ‘kickback’ to induce the referral of other federal business, one would expect that Omnicare’s pricing would be related to the size of the other federal business.”).

^{41/}Doc. [117-1](#) at 4-5.

^{42/}*See, e.g., Bessemer & Lake Erie R.R. v. Seaway Marine Transp.*, 596 F.3d 357, 369 (6th Cir. 2010) (“Given these shortfalls in Bessemer’s compliance with its discovery obligations, the district court did not abuse its discretion in excluding evidence of lost-profits damages”; *Younglove Constr. v. PSD Dev., No. 3:08-CV-1447, 2011 WL 1884540, at *1 (N.D. Ohio May 18, 2011)* (“The lack of pretrial discovery, and, at this late date any opportunity to conduct meaningful discovery as to PSD’s fee claim are important factors in my decision.”)).

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against the government at those SNFs.^{43/} Instead, he asserted in his initial disclosures that he was seeking damages for “each false claim to federal healthcare programs resulting from violations of the Anti-Kickback law”;^{44/} in other words, he said he would seek to recover for every claim that was false because it was based on kickbacks. This is sufficiently to allow him to offer evidence of Part D and Medicaid claims and payments.

Accordingly, Omnicare has had sufficient notice of the damages Gale seeks, and Rule 54 allows Gale to prove those damages to the jury.

B. Effect of the Previous Settlement

Omnicare says that its previous settlement with the United States should bar some or all of the Part D and Medicaid damages that Gale seeks under theories of double recovery, election of remedies, res judicata, and release.^{45/} Its argument goes like this: the United States, through a relator, has already brought a suit under the False Claims Act to recover all claims against federal health insurance providers at certain SNFs because the United States believe they were false due to different kickbacks. The United States and Omnicare settled that suit, among others, with a release of claims related to that conduct in exchange for a money payment. Therefore, the United States, through another relator, recover those same claims under a different theory of why those claims were false. The United States has already released its claim that those Part D and Medicaid payments were based on fraudulent information.

This argument makes some sense, at least for those facilities that allegedly received both

^{43/} See Doc. [125](#).

^{44/} Doc. [117-3](#) at 2.

^{45/} Doc. [117-1](#) at 6-15.

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kickbacks. However, Omnicare did not assert the defenses of election of remedies or res judicata in its answer.^{46/} And although it did assert the affirmative defense of release, it affirmatively withdrew that defense in its response to Gale's motion for partial summary judgment.^{47/} [Federal Rule of Civil Procedure 8\(c\)](#) specifically states the defenses of res judicata and release must be in the answer.^{48/} And the Courts of Appeals have held that election of remedies and set-off also must be pleaded in the answer.^{49/} Accordingly, Omnicare may only assert one of these defenses if the Court grants leave under [Federal Rule of Civil Procedure 15\(a\)\(2\)](#), which tells the Court to freely grant leave "when justice so requires."^{50/}

Here, justice does not so require for two reasons. First, Omnicare seeks leave to raise these defenses just over one month before the trial and just over three weeks before the original close of discovery.^{51/} If the Court had not decreased the amount of time for Gale to respond to the motion, the motion would not have been ripe until the business day before the original close of discovery.^{52/} Allowing Omnicare to assert a new defense would entitled Gale to discovery on the factual basis for the defense, such as which facilities were the subject of the settlement. With less than three weeks

^{46/}See Doc. [42](#) at 45-49.

Although the Court is aware of one Court of Appeals that has held that double recovery is not an affirmative defense that can be waived, see [Abou-Khadra v. Mahshie](#), 4 F.3d 1071, 1079 n.7 (2d Cir. 1993), there is no legitimate claim for double recovery here. Omnicare did not admit liability in the prior settlement and agree to damages for that liability; instead, it agreed to be released from the claims at issue in that case in exchange for a money payment. Doc. [117-8](#) at 6-8. Accordingly, no double recovery is at issue.

^{47/}See Doc. [83](#) at 4 n.2, 18.

^{48/}[Fed. R. Civ. P. 8\(c\)](#).

^{49/}See [Arch Ins. Co. v. Precision Stone, Inc.](#), 584 F.3d 33, 42 (2d Cir. 2009) ("[I]rrespective of whether a setoff claim is properly characterized as an affirmative defense or a compulsory or permissive counterclaim, it must be set forth in the pleadings to provide a basis for relief." (citations omitted)); [Bagwell v. Susman](#), 165 F.2d 412, 415 (6th Cir. 1947) ("Election of remedies is an affirmative defense, and should be pleaded.").

^{50/}[Fed. R. Civ. P. 15\(a\)\(2\)](#).

^{51/}See, e.g., [Hageman v. Signal L.P. Gas, Inc.](#), 486 F.2d 479, 484 (6th Cir. 1973) ("Notice and substantial prejudice to the opposing party are critical factors in determining whether an amendment should be granted.").

^{52/}The Court has since granted a joint motion to extend discovery two days, to October 2, 2013. Doc. [127](#).

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before the trial, there is insufficient time for Gale to be able to properly respond to Omnicare's new defense.

But second, Omnicare could have asserted this defense to Gale's damages claim all along. Omnicare's argument that its previous settlement with the United States should release or set-off Gale's claims for Part D and Medicaid damages at the overlapping facilities is equally valid for Gale's claim for statutory damages: just as the United States released its claim to recover Part D and Medicaid claims made by Omnicare for patients at those facilities, it released its claim to recover the statutory damages as well. Omnicare had this potentially meritorious defense to Gale's damages from the beginning of the lawsuit but only seeks to invoke it now. Indeed, it affirmatively withdrew the defense even though it could have decreased any award of statutory damages against Omnicare. Omnicare made the decision not to assert this previous settlement as a defense to Gale's claim for statutory damages at those facilities that might overlap; it must now live with that decision.

III. Conclusion

For the foregoing reasons, the Court **DENIES** Defendant Omnicare's motion in limine and **DENIES** Omnicare leave to assert a defense based on a previous settlement agreement with the United States.

IT IS SO ORDERED

Dated: October 1, 2013

s/ James S. Gwin

JAMES S. GWIN
UNITED STATES DISTRICT JUDGE