

Omnicare Settles Two Qui Tam Cases Alleging “Swapping” Kickbacks to Nursing Homes

The pharmacy provider agrees to pay US\$124 million to resolve allegations of below-cost discounts.

On June 25, the Department of Justice (DOJ) announced that it had settled with Omnicare, Inc. in two matters alleging that kickbacks resulted from below-cost discounts offered to skilled nursing homes as an inducement to select Omnicare as their pharmacy provider.¹ The cases, captioned *United States ex rel. Gale v. Omnicare*, and *United States ex rel. Silver v. Omnicare*, are both *qui tam* whistle blower cases that will be resolved by the US\$124 million settlement.

These cases are just two of the many cases filed recently alleging such swapping schemes. But this settlement is by far the largest reached in a swapping case to date. Because Omnicare is one of the largest providers serving nursing homes, this settlement may motivate whistleblowers to file even more of these types of cases in the future.

Settled Cases

In *Gale*, which was filed by Donald Gale on January 19, 2010, the relator alleged a so-called “swapping” kickback scheme in which Omnicare traded heavy discounts on prescription drugs for Medicare Part A patients in exchange for the right to service the nursing home’s Medicaid and Medicare Part D patients.² The DOJ declined to intervene in the action on April 8, 2011.

Silver, which was filed by relator Marc Silver on March 4, 2011, alleged very similar facts to the *Gale* complaint.³ On February 9, 2013, the DOJ declined to intervene in the action.

Swapping Arrangements

The swapping arrangements alleged in *Gale* and *Silver*, in which Part A discounts are traded for Part D patients, can form the basis for a False Claims Act (FCA) case because the discounts (if they constitute remuneration and are offered with the appropriate intent) could be found to be kickbacks given to induce the guaranteed Part D business.⁴

As background, prescription drug coverage for nursing facility residents is generally covered by Part A for the first 100 days of each patient’s stay, after which prescription drug coverage would be provided by Medicaid or Part D, depending on a patient’s financial status. Nursing homes have an incentive to reduce costs for their Part A residents because Medicare provides a fixed per diem rate to the nursing facility for Part A residents, regardless of the actual cost of caring for that person. The facility must cover all costs related to that patient out of that per diem amount.

In contrast, an entity providing services for residents who are covered by Part D for prescription drugs, submit expenses directly to the Medicare program.⁵ Cases alleging violations of the Anti-Kickback Statute (AKS) and FCA based on “swapping” arrangements rely on the theory that the discount is only offered on the Part A patients in exchange for a commitment from the nursing facility that the supplier (*i.e.*, Omnicare) will be the provider to all Part D patients — and have the right to charge the government the full price for those patients. The government (and, increasingly, *qui tam* FCA relators) argue that these arrangements run afoul of the AKS and therefore result in tainted false claims being submitted to the government.⁶

Case History

In both *Gale* and *Silver*, the relators based their allegations generally on a swapping/discount scheme which Omnicare allegedly developed to secure Part D and Medicaid nursing facility patients. Omnicare allegedly offered a number of kickbacks to nursing facilities, including extremely low per-diem pricing, discounts, and even below-cost pricing, in return for referrals for Part D patients that Omnicare could bill directly to government healthcare programs at full price.

After the government declined intervention in *Gale*, Omnicare moved to dismiss the case under Federal Rules of Civil Procedure 9(b) and 12(b)(6).⁷ The court granted in part and denied in part the motion. The court limited the relator’s potential claims to those arising after January 2004 under the FCA’s six-year statute of limitations. The court also found that the relator had not sufficiently alleged a violation of an alleged Medicaid “most favored customer” rule because such a rule did not exist. Rather, the statute only required that Medicaid not be charged more than Omnicare’s “usual and customary charges,” and relator had not alleged that Omnicare had exceeded that limitation. The court dismissed relator’s reverse FCA allegations as well, finding that he had merely attempted to “bootstrap” these allegations onto his other claims without any additional facts to support them. The court allowed the remainder of the complaint (containing the bulk of the FCA allegations) to proceed, finding that relator’s specific dates, drug costs, and claim submission practices were sufficient to support his claims under Rule 9(b) and Rule 12(b)(6).

Following this decision, Gale moved for partial summary judgment.⁸ He claimed that no material facts were disputed regarding whether kickbacks had been paid to one particular pharmacy, Montefiore, and that a number of Omnicare’s affirmative defenses had no merit. The court analyzed the evidence supporting Gale’s swapping allegations for Montefiore, and noted that Omnicare had raised sufficient evidence to create a triable issue of material fact as to whether the price reductions would qualify as remuneration under the AKS.⁹ Particularly, the court found that both parties offered evidence as to whether Omnicare intended to induce referrals and as to the fair market value of the products Omnicare provided to Montefiore (Omnicare claimed that competitor’s prices in the industry were evidence of fair market value, whereas Gale claimed that only Omnicare’s own “usual and customary” pricing was relevant). The court denied Gale’s motion for summary judgment as to Omnicare’s affirmative defenses regarding compliance with the discount safe harbors to the AKS, finding this determination too closely tied up in the merits of the action. The court, however, granted his motion as to its unclean hands affirmative defense as a claim that should be brought by the United States in a separate proceeding to determine the relator’s share of any recovery.

The *Silver* case, on the other hand, has not yet proceeded past the motion to dismiss stage. Currently motions to dismiss by Omnicare and the other defendants are still pending.

Settlement Agreement Resolves *Gale* and *Silver*

The ruling on Gale’s motion for summary judgment was filed on July 23, 2013. On October 23, 2013 (five days before the *Gale* trial was set to begin), Omnicare announced it had reached a US\$120 million

settlement in principle with Gale. Although the DOJ had declined to intervene in this matter, the government always has the right to approve settlements brought in its name under the FCA. Here, the DOJ appears to have nudged the settlement payment upward slightly, from the \$120 million that Omnicare originally announced to US\$124.24 million, of which US\$8.24 million would cover Medicaid claims and be distributed to various state Medicaid programs. The remaining US\$116 million will be divided between the United States and Gale, with Gale receiving a 13.8 percent share of the total settlement, or US\$17.24 million.

Very little information is available regarding what part the *Silver* case may have played in the settlement negotiations, or whether the small increase in the settlement amount was due to the agreement to also dismiss Omnicare from the *Silver* matter. Omnicare had previously alleged that Silver's complaint was merely "parasitic," "late-comer" litigation based entirely on the *Gale* complaint.¹⁰ Unlike Gale, who worked as a pharmacist for Omnicare for 16 years and alleged personal knowledge of charging and billing practices, Silver was a nursing home operator who never worked for Omnicare. The *Silver* court had not yet decided Omnicare's motion to dismiss Silver's third amended complaint as of the date the DOJ announced the settlement agreement.

Since 2006, Omnicare has been operating under a series of corporate integrity agreements (CIAs) with the Office of Inspector General (OIG). Omnicare's current CIA is set to expire in November 2014. What effect, if any, the *Gale/Silver* settlement will have on Omnicare's obligations under that CIA remains unclear, and the settlement contemplates no new CIA. This most recent settlement is Omnicare's fourth large settlement with the United States in less than eight years. Previous settlements included a US\$50 million settlement in 2012, a US\$98 million settlement in 2009 and a US\$50 million settlement in 2006. The 2009 and 2006 settlements both resulted from *qui tam* suits alleging AKS violations.

Practice Pointers

Although the legal boundaries of appropriate discounting arrangements continue to be litigated through swapping cases, healthcare entities can employ certain strategies to minimize the risks of these arrangements. Taking steps to ensure that any discounts given do not result in below-cost pricing is important, as is ensuring that diligent efforts are undertaken to collect any outstanding debts (or at least that such debts are not written off without proper justification). Sales employees should be trained not to make statements during negotiations that could be used to show an intent to provide below-cost or below-fair market value pricing on Part A services in exchange for services reimbursable directly by the government. Finally, legal counsel should analyse discounts and other pricing arrangements to determine what risks those discounts create and how those risks could be mitigated.

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Endnotes

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- ¹ Department of Justice Press Release, “Nation’s Largest Nursing Home Pharmacy Company to Pay \$124 Million to Settle Allegations Involving False Billings to Federal Health Care Programs,” available at <http://www.justice.gov/opa/pr/2014/June/14-civ-670.html> (June 25, 2014).
 - ² *United States ex rel. Gale v. Omnicare, Inc.*, No. 1:10-CV-00127 (January 19, 2010).
 - ³ *United States ex rel. Silver v. Omnicare, Inc.*, No. 1:11-CV-01326 (March 4, 2011).
 - ⁴ Claims that are submitted to the government in violation of the Anti-Kickback Statute are actionable as false claims under the FCA.
 - ⁵ Similarly, patients covered by Medicaid are charged directly to Medicaid and are not typically covered by a per diem payment arrangement with the nursing facility.
 - ⁶ For a more thorough discussion of swapping schemes and the increased enforcement activities surrounding these types of cases, see Katherine Lauer, Amy Hargreaves and Kasey Branam, *Swapping for Good: How the Rise in False Claims Act Cases Involving ‘Swapping Schemes’ Undermines Health Care Providers’ Ability to Seek Discounts as the Legislature and Regulators Intended*, *AHLA Connections*, March 2014.
 - ⁷ *Gale*, No. 1:10-CV-00127, Docket No. 26 (January 27, 2012).
 - ⁸ *Id.*, Docket No. 82 (June 7, 2013).
 - ⁹ *Id.*, Docket No. 104 (July 23, 2013).
 - ¹⁰ *Silver*, No. 1:11-CV-01326, Docket Nos. 59, 105 (August 30, 2013 and December 6, 2013).