

Lessons From Omnicare Settlement In 'Swapping' Cases



Katherine Lauer
Latham & Watkins LLP



Amy Hargreaves
Latham & Watkins LLP

Law360, New York (July 21, 2014, 2:35 PM ET) -- On June 25, the U.S. Department of Justice 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. 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 \$124 million settlement.

In Gale, which was filed by Donald Gale on Jan. 19, 2010, the relator alleged a so-called "swapping" kickback scheme in which Omnicare was alleged to have traded heavy discounts on prescription drugs covered under Medicare Part A in exchange for the right to service the nursing home's residents whose drugs were covered under Medicaid and Medicare Part D. 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. On Feb. 9, 2013, the DOJ declined to intervene in the action.

These cases are just two of the many cases filed recently alleging similar swapping schemes. But this settlement is by far the largest 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. Providers would be well-served to take steps to understand the concerns raised by discounts on services provided to entities serving different types of government patients.

Swapping Arrangements

The swapping arrangements alleged in *Gale and Silver*, in which Part A discounts are traded for Part D business, 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.

As background, prescription drug coverage for nursing facility residents is generally covered by Part A for the first 100 days of each resident's stay, after which prescription drug coverage would be provided by Medicaid or Part D, depending on the resident'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 items or services for residents who are covered by Part D for prescription drugs submits claims directly to the Medicare program. Cases alleging violations of the Anti-Kickback Statute (AKS) and FCA based on "swapping" arrangements rely on the theory that the discount is offered only on items or services provided to residents covered under Part A in exchange for a commitment from the nursing facility that the supplier (e.g., Omnicare) will be the provider to all residents covered under Medicaid or Part D — and have the right to charge the government Medicare and Medicaid rates. The government (and, increasingly, qui tam FCA relators) has taken the position that such arrangements run afoul of the AKS and therefore result in tainted false claims being submitted to the government.

The Office of Inspector General for the U.S. Department of Health and Human Services (OIG) has released numerous opinions and compliance program guidance documents addressing such swapping arrangements. Through these publications, the OIG has established the following four principles regarding swapping arrangements:

- "Any link or connection, whether explicit or implicit, between the price offered for business paid out of the purchaser's pocket and referrals of Federal program business billable by the ... supplier will implicate the anti-kickback statute."
- "The size of the discount is not determinative ... the appropriate question to ask is whether the discount is tied or linked, directly or indirectly, to referrals of other Federal healthcare program business."
- Although "any link" may implicate the AKS, in order to determine if there should be an inference of an "improper nexus" between discounts and referrals, the government will "look for indicia that the discounted rate is not commercially reasonable in absence of other, non-discounted business."
- While the AKS contains a specific statutory exception for discounts and a regulatory safe harbor was established, these so-called swapping arrangements are illegal remuneration that do not fall within either because those protections were meant solely for arrangements that benefit Medicare or Medicaid.

While these general guidelines have provided some assistance to providers in understanding the OIG's concerns regarding swapping and discounting arrangements, very few courts have weighed in on the issue. Instead, some swapping cases are currently pending, and others have been settled without adding

to the case law on this issue. The Gale and Silver cases must now be added to the list of settled swapping cases.

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 business. Omnicare allegedly offered a number of kickbacks to nursing facilities, including extremely low per-diem pricing, discounts, and even below-cost pricing on Part A business, in return for referrals for Part D and Medicaid business 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). 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. 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. In particular, 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, did not proceed past the motion to dismiss stage. Motions to dismiss by Omnicare and the other defendants were still pending when the settlement was announced.

Settlement Agreement Resolves Gale and Silver

The ruling on Gale's motion for summary judgment was filed on July 23, 2103. On Oct. 23, 2013 (five days before the Gale trial was set to begin), Omnicare announced it had reached a \$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 \$124.24 million, of which \$8.24 million would cover Medicaid claims and be distributed to various state Medicaid programs. The remaining \$116 million will be divided between the United States and Gale, with Gale receiving a 13.8 percent share of the total settlement, or \$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. 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.

Practice Pointers

Although the OIG's opinions and guidance discussing swapping and discounting arrangements can be helpful, they are largely too narrow or vague to provide the comprehensive set of discounting rules that would be truly helpful for providers. Therefore, healthcare entities must take steps to ensure that they fully understand the issues undergirding discounting arrangements to protect themselves as much as possible from qui tam lawsuits alleging kickbacks.

Providers should be aware that there may be some circumstances where a discounting arrangement may fall within the AKS's discount safe harbor and/or statutory exception. The OIG has concluded that neither would apply to typical discount arrangements unless the discounted rate is also charged directly to Medicare Part B or D or Medicaid. However, the OIG's Advisory Opinion 13-07 provided that where rebates were given based on total annual purchases regardless of whether the items were covered by federal health programs, the discount safe harbor may apply. Because this type of discount does not distinguish between Part A or Part B/D or Medicaid, the discount could be attributed to each product individually. Providers may want to structure discount arrangements to more closely mirror the arrangement described in Advisory Opinion 13-07 to reduce the risks of AKS violations.

An understanding of what constitutes "remuneration" under the AKS is also important when entering into discounting arrangements. Fair market value is the relevant standard by which a court or agency would determine whether any kickbacks had been paid under the arrangement. But defining fair market value is extremely difficult, as demonstrated by the court's decision on the Gale motion for summary judgment. As discussed above, the Gale court punted on the fair market value issue at the summary judgment stage because Omnicare and Gale had argued that different standards should be applied in determining fair market value, and the court was unable to reach a decision on the issue. Gale felt that only Omnicare's own "usual and customary" pricing was evidence of fair market value, but Omnicare argued that competitor's prices were relevant. The OIG has not taken a position on this, alternatively arguing that cost, fair market value, or the competitive market should provide the starting point for any analysis under the AKS. Relators have often argued that the Medicare Fee Schedule is a proxy for fair market value, but no cases or advisory opinions have supported this argument. Any provider entering into a discounting arrangement should carefully analyze the market factors to determine whether any proposed discount could be considered remuneration under the AKS.

In short, health care entities would be well-served by:

- Taking care to structure discounting arrangements in a way that does not suggest any quid pro quo.
- Carefully analyzing fair market value and ensuring any discount does not result in remuneration.
- Considering basing discounts on volume, similar to what was approved by the OIG in Advisory Opinion 13-07.

Given the lack of guidance, it is likely these issues will continue to be litigated. The Omnicare settlements, while not adding to the substantive case law, do demonstrate that these swapping cases will likely become more common in the coming years as more qui tam relators are tempted by these and other large settlements.

—By Katherine A. Lauer and Amy E. Hargreaves, Latham & Watkins LLP

Katherine Lauer is a partner in Latham & Watkins' San Diego, California, office and global co-chairwoman of the firm's health care and life sciences practice.

Amy Hargreaves is an associate in the firm's San Diego office.

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