Omnicare Settlement Suggests Greater Anti-kickback Scrutiny of Providers' Supply Agreements

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On June 25, 2014, the United States Justice Department announced that Omnicare, Inc. has agreed to pay $124 million to settle allegations that it offered improper financial incentives to skilled nursing facilities in return for their continued selection of Omnicare, Inc. to supply drugs to Medicare Part D and Medicaid beneficiaries residing in their facilities. This settlement resolves two complaints alleging that Omnicare, Inc. participated in improper 'swapping arrangements' with long term care facilities in violation of the Anti-Kickback Statute (AKS) and may signify a renewed anti-kickback enforcement focus area for the Department of Justice going forward. Diligent providers should heed the warning and review their supply agreements for anti-kickback compliance—not just those with Omnicare, Inc. but also with other third party providers. Notably, these settlements were made in cases brought by *qui tam* relators where the government decided not to intervene.

Generally, the number of alleged Anti-Kickback Statute violations has increased dramatically since passage of the Affordable Care Act, which made many AKS violations *per se* False Claims Act violations, thereby increasing the potential civil monetary penalties available to the government in prosecuting such claims. Allegations of improper swapping arrangements have increased accordingly. The Omnicare settlement resolves two such cases: *United States ex. rel Gale v. Omnicare, Inc.* and *United States et al. ex rel. Silver v. Omnicare, Inc.*, each of which is detailed below.

United States ex rel. Gale v. Omnicare

In 2013, Omnicare, Inc., the nation's largest provider of pharmaceuticals and pharmacy services to long-term care facilities, attempted to settle a pending *qui tam* lawsuit brought by an Omnicare employee in Ohio for $120 million, which asserted that it participated in a 'swapping arrangement' in violation of the AKS statute. The relator (Mr. Gale) was a former pharmacy consultant, director, director of operations, vice president of operations, and general manager of an Omnicare pharmacy in Ohio and alleged that Omnicare was unlawfully offering discounted or below-cost pharmaceutical services for the facility's residents covered under Medicare Part A as inducement for facilities to increase referrals to Omnicare of residents whose drugs were covered by Medicare Part D. The whistleblower's claim described a prototypical swapping arrangement in violation of the AKS, alleging that Omnicare intentionally provided discounted prescription drugs for Medicare Part A residents and absorbed the loss as a strategy to increase the volume of drugs it was allowed to provide to Medicare Part D residents residing in the same facilities. The Department of Justice declined to intervene in the action but later blessed the privately negotiated June 2014 settlement.

United States ex rel. Silver v. Omnicare

The Silver case, which was filed by relator Marc Silver on March 4, 2011, alleged very similar facts to Gale. Silver was a nursing home operator who never worked for Omnicare and asserted in his complaint that Omnicare created a kickback scheme in which, in order to become the institutional pharmacy of choice to a nursing home, it "underpriced Medicare Part A drugs sold to the nursing home in exchange for the opportunity to provide the same drugs, at a higher cost, to the nursing home's Medicaid, Medicare Part D, and privately insured patents." The complaint asserted that since this discount arrangement did not fall under the discount safe harbor of the AKS, it amounted

to an Anti-Kickback violation. The Department of Justice also declined to intervene in this action but agreed to the June 2014 settlement.

Swapping Arrangements

Swapping arrangements, such as those described in the two Omnicare cases, originate out of the different reimbursement rates Medicare assigns when the same drug is given to a Medicare Part A versus a Medicare Part D nursing home resident. Specifically, Medicare Part A pays a flat per diem rate for all treatments given to a resident during their first 100 days of stay in a nursing home (the flat rate includes reimbursement for any prescription drugs administered to the resident during this time, providing no separate opportunity for the nursing facility to bill for and recover the prescription drug's costs). After the first 100 days, however, either Medicare Part D, Medicaid, or private insurance pays the costs of any prescription drugs provided to residents at the provider's 'usual and customary price' or a lower negotiated amount. As a result, nursing homes may maximize profits during a resident's Part A stay only by either minimizing the care provided to such resident or minimizing the costs incurred in providing such care. The above described claims alleged that Omnicare, recognizing this cost structure, sold drugs targeted for Part A residents to nursing homes at a discounted rate, thus helping the nursing home maximize profits on the front end and encouraging its selection as the institutional pharmacy provider for the facility to enable it to obtain more referrals of Part D prescription drug orders overall, for which it charged higher rates. Essentially, Omnicare would swap losses it incurred in supplying drugs to Part A residents at a discounted rate for the higher profits available in supplying drugs to the nursing home for Part D residents as the institutional pharmacy of choice for the facility.

The Silver complaint alleges in detail that Omnicare could afford to engage in this kickback scheme due to the typical payor demographics in nursing homes. Often, only 10-15% of nursing home residents are covered by Part A, with the remaining 85-90% of residents covered by Part D, Medicaid or private insurers. Consequently, any losses incurred by Omnicare in providing discounted drugs for Part A residents were more than recovered by providing drugs to the remaining, higher paying residents.

Practical Pointer

With these cases in mind, nursing homes should diligently review their existing pharmaceutical and other supplier agreements to ensure that (i) any discounts negotiated do not result in it obtaining goods or services at below cost; (ii) negotiated prices represent fair market value for items/services provided to all categories of residents; and (iii) neither contractual language nor documentation of contract negotiation processes are suggestive of the intentional creation of swapping arrangements. Sales employees should be trained on permissible statements to be made in negotiations and any contracts attempting to offer discounts or disparate pricing arrangements for different categories of patients should be scrutinized by legal counsel before being executed, with the entire practice minimized as much as possible.

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