

Bundled Sales: Anti-Kickback Concerns

Tom Bulleit

ROPES
& GRAY

FHCP Anti-Kickback Law

- Felony to offer, pay, solicit, or receive “remuneration” (anything of value) to induce the referral of a patient, or the purchase, order, or lease (or the arranging for or recommending) of any item or service that may be paid for by Medicare or another FHCP. 42 U.S.C. 1320a-7(b)
- “One Purpose” Test Implicates All Sales Programs for Devices Used in Treatment of FHCP Patients
- Extensive Application to Pharma Pricing and Sales Programs
- Nascent Application to Device Pricing and Sales Programs

FHCP Anti-Kickback Law

- Pertinent Exceptions and Safe Harbors Related to Bundled/Packaged Sales
 - Safe Harbor: Properly Reported Discounts
 - Safe Harbor: Warranties
 - Safe Harbor: GPO Fees
 - No Safe Harbor for:
 - Unreimbursed Medical Expenses
 - Free Products or Services that do not qualify as discounts

Discount Application to Bundled Sales

- Prohibited: Discounts on A to Induce Purchase of B, UNLESS items reimbursed under “same methodology and the reduced charge is fully disclosed to the [FHCP] and accurately reflected where appropriate and as appropriate to the reimbursement methodology”
- Consider application in:
 - Capital placement programs
 - “Giving away” or discounting capital in order to sell disposables requires adherence to certain standards in order to meet safe harbor
 - “Cross divisional” programs
 - “Good customer” discounts

Olympus Corp of America

- DPA USAO NJ March 2016
 - \$612 Million/36 Month Monitorship
- Covered Conduct
 - “Grants, payments for travel and recreational activities, consulting payments, and gifts or no-charge loans of Olympus equipment.”
 - Loans of endoscopes, value “\$20k or more,” “in order to win business and induce purchases of Olympus products”:
 - Donation of tens of thousands in equipment to “neutralize” competitor efforts
 - \$400k in endoscopes to doctor believed to have role in hospital purchasing
 - Donation to hospital system for new hospital because “we need access for potential sell of \$300k”
 - Program for no-charge loans for months and sometimes more than a year “for the express purpose of inducing customers to purchase that equipment.”
 - When leases ended, allow customers to keep old equipment and skip several months of payment in order to induce new lease
- **Strict compliance with discount safe harbor requirements becomes even more crucial**

Warranty Safe Harbor

- Safe Harbor Permits Seller warranties that are part of basis for the original sale provided certain requirements are met
 - Competitive Replacement Programs permitted

Selected Antitrust Issues Relevant to Product Sales

- Antitrust violations under the Sherman Act, the Clayton Act, or the Robinson-Patman Act, may arise in the following contexts:
 - Tying - conditioning the purchase of one product on the purchase of another product
 - Bundling - a rebate or discount for buying both products
 - Volume discounts based on the customer buying a certain amount or percentage of requirements
 - Exclusive dealing
 - Product redesign to foreclose competition (similar to tying)
 - Price discrimination
- Each of the above may be lawful or unlawful depending upon the circumstances, usually Market Power