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Emerging Life Sciences Companies

second edition

Chapter 19

What Medical Technology Companies Should Know About Program Integrity Issues Arising from Reimbursement and Marketing

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WHAT MEDICAL TECHNOLOGY COMPANIES SHOULD KNOW ABOUT PROGRAM INTEGRITY ISSUES ARISING FROM REIMBURSEMENT AND MARKETING

Emerging companies focused on drugs, devices, and related technology should be aware of the potential for government and private enforcement action regarding alleged fraudulent reimbursement and marketing activities and false claims. The following outline briefly summarizes the principal laws in this area, theories of prosecution, sources of guidance, and suggested areas of focus to reduce the potential for such claims.

Federal False Claims Act (31 U.S.C. § 3729) (FCA)

A. Elements of a violation: knowingly presenting, or causing to be presented, a claim that is false or fraudulent

B. Criminal and civil (damages may be trebled, plus $5,500 to $11,000 per claim) penalties apply (plus program exclusion)

C. "Qui tam": Allows private right of action to encourage assistance in combating fraud

D. Percentage of award available for qui tam "relators"

1. 15% to 25% if government intervenes

2. 25% to 30% if no government intervention

States Enhancing/Supplementing False Claims Statutes

A. Almost half of the states have false claims statutes

B. Approximately 15 states have whistleblower provisions, with more under consideration

C. State false claims statutes have a variety of "falsity" standards

D. Manufacturers/providers could face multiple cases in different states using different standards

Theories of Prosecution

A. Facially false claims (any defect in claim itself or generation of claim (e.g., improper code))

B. Tainted claims

   1. Kickback-induced

   2. Use for an indication that is not a medically accepted indication (see, e.g., Neurontin)

   3. Improper commercialization/reimbursement of investigational products

   4. Pattern of unreported adverse events (see, e.g., Guidant, Dentsply)

Other Guidance and Resources for the Reimbursement Professional

A. When a manufacturer acts as a provider/supplier: Beneficiary Inducement Prohibition (Soc. Sec. Act § 1128A(a)(5))

   1. Elements of a violation: offer/transfer remuneration to beneficiary that you know or should know is likely to influence a beneficiary's choice of provider

   2. Limited exceptions: inexpensive gifts, preventive care, among others

   3. CMP penalties apply: $10,000 per item/service, plus three times amount claimed, plus potential exclusion

B. When a manufacturer acts as a consultant: "Practices of Business Consultants," OIG Special Advisory Bulletin (June 2001)

C. Advisory opinions: an important resource, potential tool for the reimbursement professional

D. Significant advisory opinions on

   1. Product bundling

      a. Bundled support surface arrangement to encourage SNF stepdown treatment

      b. Comprehensive wound care program for SNFs; manufacturer at risk for failure of products to yield treatment outcome

   2. Patient assistance programs

      a. Grants by nonprofit charitable organization to financially needy patients for costs of prescription drugs

      b. Provision of financial assistance by nonprofit foundation established by drug company to subsidize cost-sharing amounts incurred by financially needy patients using its drugs

c. Patient assistance program by drug company that provides payment of Medicare Part B or Medicare Part D cost-sharing amounts for financially needy beneficiaries using its drugs

3. Reimbursement guarantees

a. Patient prequalification for reimbursement, credits for denied claims

b. Purchase price refund for denials of new blood-filtering device

E. Don't forget State attorneys general

Case Studies on Reimbursement Advice

A. Augustine Medical

1. Operation Headwaters case

2. Warm-Up Active Wound Therapy device

3. Government allegations included

a. Advocated billing strategy that concealed true nature of product

b. Denials concealed from customers

c. Discouraged/controlled customer communications with other customers

4. The outcome

a. Former CEO, general counsel, national sales manager, and reimbursement director pled to withholding material facts concerning coverage and reimbursement status

b. Outside reimbursement consultant pled to felony crime of healthcare fraud

c. Augustine Medical ordered to pay $5.2 million in criminal fines and placed on probation for five years for knowingly/willingly withholding material facts concerning Medicare coverage and reimbursement status; the company also paid $7.5 million in civil penalties and was excluded

B. Huntleigh Technology

1. Lymphedema pumps

2. Early 1990s: Utilization spike triggered initial scrutiny of suppliers

3. Government allegations included causation of upcoding to E0652

4. Outcome: In 1995, Huntleigh settled for $4.9 million; supplier investigations damage relationships

C. Lessons learned

1. Develop a compliant reimbursement strategy early in product development

2. Exercise care in communications with CMS, its contractors, and the manufacturer's customers

3. It is not difficult to indirectly "cause" the submission of a false claim

Increasing Accountability for Indirect Behavior: Don't Do Indirectly What You Can't Do Directly

A. Distribution arrangements (e.g., copromotion, SPFs)

B. Consultants

C. Group purchasing organizations (GPOs)

1. Device manufacturer may be found to have caused the filing of a false claim by a distributor if it knows the providers receiving products file claims and that the terms of its distributor arrangements may violate healthcare laws.

Perspectives on Sales Force Training for the Reimbursement Professional

A. How are salespersons getting the message now?

B. What is your role?

C. When does training begin?

D. Maintaining control in payor communications, customer communications

E. Working in partnership—sales and marketing can provide useful field intelligence