Operativ FCA Guidelines 1/30/14

Operativ False Claims Guidelines

Employees to read annually.

This set of guidelines explains Operativ's internal policies that are intended to ensure compliance with the False Claims Act. It is a companion document to Operativ's Code of Ethics.

Guideline 1

Any items or teaching materials offered to referring individuals will primarily entail a benefit to patients and will not be of substantial value. Accordingly, textbooks, modest meals, images, content for brochures, content for websites will be determined to be of primary benefit to patients, serve a genuine educational function, and be of no cash value. Accordingly, textbooks and other educational material must primarily benefit patient care and have no commercial value to the physician.

No items or other material will be offered to referring individuals that could affect the judgment of individual practicing providers.

Any meals must be a modest meal. Breakfast allowance=\$25/person, Lunch allowance = \$50/person & Dinner allowance = \$125/person. Incidental snack/coffee=\$15/person.

When educational meetings occur in conjunction with a social event such as a meal, the educational component must have independent value, such as a presentation by an authoritative speaker, other than a sales representative of the company.

Also, the meal should be a modest one similar to what a physician routinely might have when dining at his or her own expense. In an office or hospital encounter with a company representative, it is permissible to accept a meal of nominal value, such as a sandwich or snack.

Gifts in the form of cash payments will not be offered. Only physicians who provide genuine services to Operativ may receive reasonable compensation. When considering the time a physician spends with an Operativ representative, it is the representative who offers a service, namely the presentation of information. The physician is a beneficiary of the service. Overall, these guidelines do not view that physicians should be compensated for the time spent participating in educational activities, nor for time spent receiving detail information from an Operativ representative. Operativ FCA Guidelines 1/30/14

Guideline 2

Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (i.e. pens and notepads).

Operativ can provide electronic content such as images and written content for brochures and websites, but Operativ cannot provide electronic equipment, such as hand held devices or computers.

Although Guideline 2 recognizes that gifts related to a physician' s practice may be appropriate, it also makes clear that these gifts must remain of minimal value. It is not appropriate for Operativ to offer expensive hardware or software equipment.

Guideline 3

The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.

Guideline 4

Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by an Operativ sales representative may create a relationship which could influence the use of the Operativ's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from Operativ by the physicians attending the conference.

Guideline 5

Operativ should not offer directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of referring individuals attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. Operativ FCA Guidelines 1/30/14

It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. **Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.**

Guideline 6

Operativ will not offer gifts, items, or remuneration with any expectations for referrals.