AVOIDING LEGAL PITFALLS: ADOPTION OF MARKETING EXPENSE BUDGET AND GIFT POLICY

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By: Jeffrey S. Baird, Esq.

The pharmacy profession is caught in a "perfect storm" of reimbursement cuts, increased government scrutiny and post-payment audits. And yet, the demand for pharmacy services will only increase dramatically as the 78 million "baby boomers" age. This convergence of events makes it even more important that the pharmacy have an innovative marketing program. It is equally as important that the marketing plan fall within legal guidelines. This is particularly so in light of the aggressive scrutiny by the government and its contractors of marketing activities by pharmacies. An important step that a pharmacy can take to insure compliance with federal laws is to adopt a Marketing Expense Budget and Gift Policy. This Q&A addresses such a policy.

Question: What is the first issue that a Marketing Expense Budget and Gift Policy ("Policy") should address?

Answer: The first issue to be addressed should be the "Marketing Mission Statement and the Underlying Law." The Marketing Mission Statement can say something like the following:

> ABC Pharmacy ("ABC") is a health care provider. It serves patients covered by various third party payors, including the Medicare program. As a health care provider, ABC understands that while it can engage in marketing activities, it cannot pay physicians and other referral sources for referrals of patients, and it cannot pay patients to induce them to obtain products and services from ABC.

The Underlying Law should then discuss the three principal federal statutes that ABC cannot violate.

1. The Medicare/Medicaid anti-kickback statute prohibits knowingly and willfully soliciting, receiving, offering, or paying anything of value to induce referrals for items or services payable by a federal health care program.

2. The beneficiary inducement statute prohibits a provider from giving anything of value to a Medicare beneficiary to influence the beneficiary to purchase an item from the provider. There is a nominal value exception to the inducement statute, which provides that a provider can give a gift to a beneficiary so long as the gift has a retail value of $10 or less and so long as the collective retail value of gifts given to any one beneficiary does not exceed $50 over a 12 month period.

3. The Stark physician self-referral statute prohibits a physician from referring Medicare/Medicaid patients to a provider (offering "designated health services") in which the physician has an ownership or compensation interest. There are several exceptions to Stark, one of which is that a provider may give non-

cash/cash equivalent items (e.g., meals) to a physician so long as the collective cost of the items does not exceed $352 during the year.

<u>Question</u>: Under the "Marketing Mission Statement and the Underlying Law" section of the Policy, do the exceptions under one statute necessarily apply to other statutes?

<u>Answer</u>: No. The nominal value exception to the beneficiary inducement statute does not apply to the anti-kickback statute. However, it is unlikely that the government will allege that a nominal value gift to a beneficiary violates the anti-kickback statute. The $380 non-cash/cash equivalent exception to Stark does not apply to the anti-kickback statute. However, it is unlikely that the government will allege that a gift that meets this exception will violate the anti-kickback statute. The beneficiary inducement statute allows gifts to Medicare beneficiaries under certain conditions. Stark allows gifts to physicians under certain conditions. None of the statutes specifically address gifts to individuals who are neither physicians nor beneficiaries. An obvious example is an employee of a physician. The anti-kickback statute broadly addresses gifts to non-physicians/beneficiaries by saying that in giving such a gift a provider cannot knowingly intend to induce a referral. It is unlikely that the government will assert a violation of the anti-kickback statute if the provider gives occasional gifts, of minimal value, to non-physicians/beneficiaries (such as an employee of a physician). The reason it is unlikely that the government will make such an assertion is because such an occasional/minimal value gift will likely not serve as an inducement for the recipient to refer patients.

<u>Question</u>: What is the second issue that the Policy should address?

<u>Answer</u>: The Policy should set out a "Marketing Expense Budget." For example, there can be a provision that says:

> In an effort to assist Account Managers ("AMs") with the sales and marketing of ABC services, each territory will have a quarterly expense budget of $__________. Quarters are based on the ABC fiscal calendar year as follows:
>
> - Q1 (January - March)
> - Q2 (April – June)
> - Q3 (July – September)
> - Q4 (October – December)
>
> This budget includes, but is not limited to:
>
> - Inservices
> - Vendor fairs
> - Marketing items, i.e. candy
> - Plants

- Gifts
- Customized AM stationery, i.e. "From the desk of…"
- "Thank You for the Referral" cards
- Meals

This budget does not include marketing items purchased with the ABC name/logo, including, but not limited to:

- Pens and pads
- Calendars
- Promotional items, i.e., mugs, clocks, candy jars, lip balm, etc.

AMs are responsible for keeping their quarterly marketing expenditures within their $___________ budget. If an AM goes over-budget in a quarter, then he/she is required to reduce expenses in the following quarter to average no more than $___________ for the two quarters in question, unless prior approval is obtained from the CO.

Question: What is the third major issue that the Policy should address?

Answer: The Policy should address **"**Gifts To Individuals Who Are Not Physicians Or Patients." For example, the Policy can say:

a. Never give a gift in exchange for a referral.

b. Gifts cannot exceed $35 in value unless prior approval is obtained from the CO.

c. Gifts must be occasional.

d. No "thank you" gifts.

e. No alcoholic beverages, gift certificates, coupons, gift cards, cash, or other cash equivalents, in any amount, unless you receive prior approval from the CO.

f. Meals and Christmas Gifts – Examples are:

- ➢ One Christmas gift basket may be delivered to employees of a physician, to be shared by the employees, so long as the purchase price of the gift basket does not exceed $50.

- ➢ Breakfast may be delivered to employees of a physician not more than four times per year so long as the purchase price of each breakfast does not, in the aggregate, exceed $35.

- Lunch may be delivered to employees of a physician not more than four times per year so long as the purchase price of each lunch does not, in the aggregate, exceed $50.

g. Training and education may be provided to employees of a physician so long as the training/education occurs locally. A meal may be provided in connection with the training/education so long as the meal is modest in cost. The AM may not pay for the employees to attend training/education not provided by ABC.

h. Reimbursement of Expense Reports may be delayed or denied if it appears that something of value was given in exchange for a referral. For example:

- Expense Reports that indicate the expenses were incurred "for referrals" or that say "thanks for referrals" (or words to that effect) will be delayed while the CO seeks clarification. Ultimately, the expenses may not be reimbursed.

- Expense Reports that imply a possible intent to induce referrals will be delayed while the CO seeks clarification. Ultimately the expenses may not be reimbursed.

- Examples of inappropriate justifications for expenditures:

  - "This is the largest referral source in the region."
  - "We are hoping to enter into a contract with this person."
  - "This person has always sent patients to ABC."

- If the intent is to market ABC, then the purpose of the expenditure should be listed as "marketing."

Question: Should the Policy also address gifts to physicians?

Answer: Yes. The Policy can say something like the following:

a. Never give a gift in exchange for a referral.

b. No alcoholic beverages, gift certificates, coupons, gift cards, cash, or other cash equivalents, in any amount, unless you receive prior approval from the CO.

c. As with gifts to non-physicians, gifts to physicians cannot exceed $35 in value unless prior approval is obtained from the CO.

d. No gifts to family members of physicians.

e. Total value of everything given to a physician in any one-year period cannot exceed $380.

- This includes, for example, any entry or green fees for a physician paid by ABC to take the physician golfing or to a sporting or other event – even if an ABC employee also participates or attends.

- This includes, for example, training and education for the physician.

- The $380 annual limitation also covers any meals, refreshments or other items or services that are provided or paid for by ABC for the physician.

f. Gifts must be occasional.

g. No "thank you" gifts.

h. No gifts to group practices, but gifts can be given to individual physicians in a group practice.

i. Gifts cannot be given if they have been solicited by physicians or their staff.

j. A physician may be compensated for consulting, research, advisory and other professional services (including out-of-pocket expenses) so long as the services have substantive value to ABC, the compensation is the fair market value equivalent to the services rendered, the arrangement is described in a contract executed by the physician and ABC, and the contract is approved by ABC's legal counsel.

Question: Should the Policy also address gifts to patients?

Answer: Yes. The Policy can say something like the following:

a. Never give a gift in exchange for a referral.

b. For Medicare and Medicaid patients:

- Each item may not have a retail value in excess of $10; the retail value of all items given in any one-year period to any one patient must not exceed $50.

c. In the event that ABC makes a mistake that results in inconvenience for a patient, then an apology gift may be given to the patient so long as the apology gift does not cost in excess of $35.

d. No alcoholic beverages, gift certificates, coupons, gift cards, cash, or other cash equivalents, in any amount, unless you receive prior approval from the CO.

e. Gifts with a retail value greater than $10 may be donated to charities, including patient advocacy groups, to benefit families and individuals in need, provided that the gifts do not specify which group (e.g., ABC patients) or which individual (e.g., Mr. Jones) is to receive the gift.

Question: Lastly, should there be disciplinary action in the event a marketing employee violates the Policy?

Answer: Yes. Any employee who fails to comply with the ABC gift policy may be subject to disciplinary action, up to and including termination. Additionally, ABC may not reimburse employees for gifts they make that violate the Policy.

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