



Issues and Compliance Strategies for Pharmaceutical Marketing

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Federal Statutes/Regulations

- Anti-kickback statute 42 USC 1320a-7b(b) (Criminal) and 42 USC 1320a-7a(7) (Civil Monetary Penalties)
- Prohibition on Beneficiary Inducements 42 USC 1320a-7a(5)
- Medicaid Rebate Issues 42 USC 1396r-8

Federal Statutes/Regulations

■ Safe Harbors

■ Discounts do not include

- Mixed goods under different reimbursement methodologies
- Reductions not offered to Medicare or Medicaid
- Routine reduction or waiver of copayment
- Warranties
- Services
- Other “remuneration”

■ Require Disclosure

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Hypothetically
speaking...

Co-Payment Coupons

Pharma company offers coupon good for the amount of the consumer's co-payment up to \$10

The coupon states that it cannot be used for Medicaid co-payments

Co-Payment Coupon Issues

- *Does the coupon affect Medicaid “Best Price” or AMP?*
- *Is there a kickback issue?*
- *Is there a beneficiary inducement issue?*
- *Does it matter if the coupon is a “one time only” offer?*
- *What other laws affect coupons?*

Marketing to the Prescriber

Pharma Company wishes to reward prescribers for their brand loyalty. Its top prescribers will receive a PDA with wireless prescribing ability. The wireless service subscription will be paid by Pharma as long as the physician prescribes more than 100 of Pharma's drugs per month.

Marketing to the Prescriber

- *Could giving prescribers the PDA affect Medicaid Best Price?*
- *Is there a potential kickback issue?*
- *How might this program be modified to decrease legal risks?*

Market Share Rebates

Pharma Company has developed an innovative new drug, Drug X, but is having trouble getting physicians to shift from competing drugs in the same therapeutic class. Pharma enters into a growth rebate agreement with a large pharmacy chain....

Market Share Rebates

The growth rebate agreement provides increasing rebates to the pharmacy chain if the sales of Drug X exceed that of previous quarters.

The rebate calculations explicitly exclude Medicaid prescriptions.

Market Share Rebates

- *Could this arrangement affect Medicaid Best Price?*
- *Is there a potential kickback issue?*
- *What other legal and business risks does this present, (i.e., what would Jim Sheehan say?)*
- *What laws should be examined in relation to this arrangement?*

Disease Management Programs

A significant number of patients with Condition F are improperly diagnosed because the condition is rare and often misdiagnosed by physicians. Even when patients are correctly diagnosed, they are often non-compliant and fail to take Drug X, manufactured by Pharma, as prescribed.

Disease Management Programs

Company A creates a disease management program, consisting of chart review services performed for physicians , prescription drug refill reminders, and a patient hotline staffed by RNs. Patients who comply are rewarded with free trips to a spa in California.

Disease Management Programs

- *Could this arrangement affect Medicaid Best Price?*
- *Is there a potential kickback issue?*
- *Is this a beneficiary inducement?*
- *What other legal risks are there?*
- *How might this program be modified to decrease legal risks?*

Free Goods

Pharma Company is disappointed with the sales of Drug X. To encourage prescriptions, it offers a health system one free unit of Drug X for every 10 prescriptions of Drug Y that are dispensed by its pharmacy.

Free Goods

- *Could this arrangement affect best price?*
- *Is there a potential kickback issue?*
- *Do FDA laws impact this arrangement, and if so, how?*

Repackaging

Pharma sells Drug X in bulk to an HMO, which repackages the drug and dispenses it under its own labeler code. Because of the volume of the sales, and preferred formulary status, the HMO gets a large discount.

Repackaging

- *Could this arrangement affect best price?*
- *Is there a potential kickback or inducement issue?*
- *Do FDA laws impact this arrangement?*