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Manufacturer Patient Support Initiatives: Current Practices and Recent Challenges

by

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The following describes several of the legal issues associated with reimbursement support programs, which broadly covers patient assistance programs, copayment assistance, benefits investigations and payer appeals, and patient educational support programs. Note that a separate paper addresses such issues as off-label promotion, False Claims Act, and State corporate practice of medicine laws.

I. **Anti-Kickback Statute**

A. Statute. Prohibits knowingly and willfully furnishing anything of value in exchange for the referral for, purchase of, or the recommending of the purchase of, items or services reimbursable under a Federal healthcare program.

1. In the context of reimbursement and patient support services, this could include under certain circumstances furnishing services of value to a physician to induce the prescribing of a manufacturer's product, or the provision of free drug or coinsurance support to a patient to induce the purchase of product covered under Medicare or Medicaid.

B. Benefits Investigation and reimbursement support services. OIG has provided some guidance as to what services can be furnished as part of a reimbursement support program, without raising significant Anti-Kickback Statute concerns, and which ones are more problematic.

1. *Compliance Program Guidance*. OIG has stated that billing or reimbursement assistance tied to a manufacturer's product is acceptable because the service has no substantial, independent value. However, if furnishing additional services, such as reimbursement guarantees, then there are Anti-Kickback Statute implications.

2. *Advisory Opinions*. The following OIG Advisory Opinions help define the contours of what is and is not acceptable to OIG.

a. *Advisory Opinion 06-16*. A manufacturer of durable medical equipment's proposal to combine billing advice services with advertising services for its customers at no charge deemed to be problematic.

b. *Advisory Opinion 02-06*. Reimbursement guarantee deemed acceptable where: (a) product covered under a national coverage decision; (b) the guarantee applied only to care covered under the national coverage decision; (c) only the cost of the product, and not the related services, was subject to the guarantee; (d) the guarantee was limited to an initial introductory period; and (e) the purchaser would be required to fully disclose to Medicare any amounts refunded under the guarantee.

c. *Advisory Opinion 00-10.* Reimbursement guarantee deemed acceptable where: (a) the drug subject to the guarantee was extremely expensive, and is sold to a Medicaid population; (b) coverage was widely available; and (c) patients were first vetted through a process that verifies that they meet payer coverage guidelines.

C. Patient assistance. OIG has also provided substantial guidance regarding patient assistance plans ("PAPs"). "PAP" generally refers to the provision of free drugs to indigent beneficiaries. However, "PAP" is sometimes a reference to coinsurance support, whereby a manufacturer subsidizes some or all of a patient's coinsurance.

1. *PAP guidance*. OIG issued guidance in November, 2005, for the purposes of allowing manufacturers to promote PAPs that interact with Part D prescription drug plans in a manner that does not raise Anti-Kickback Statute liability. Acceptable models include the following:

a. *Independent Charity PAPs*.

(i) **Structure**. One or more manufacturers makes cash donations to an independent, bona fide charity.

(ii) **Desirable characteristics**.

(a) No manufacturer exerts any direct or indirect influence over the charity.

(b) The assistance to beneficiaries is independent from any manufacturer's funding.

(c) The assistance is not tied to use of a particular manufacturer's product, or the receipt of items or services from a particular provider or supplier.

(d) Assistance is rendered based on reasonable and uniform measures of financial need.

(e) No manufacturer receives any data that would allow the manufacturer to determine the extent to which there is a correlation between the manufacturer's donations and the number of prescriptions of their products.

(f) Aggregate data about the number of applicants needing assistance with respect to a particular disease category is acceptable. Disease categories must be defined broadly.

(iii) This assistance should qualify towards a Part D enrollee's true out-of-pocket costs ("TrOOP").

b. *Outside Part D Model*.

(i) **Structure**. Beneficiaries receive specific drugs through a manufacturer's PAP, without any coverage under Part D.

(ii) **Desirable characteristics**.

(a) PAP notifies Part D plans to ensure that no payment is made from the Part D plan.

(1) CMS data sharing agreement facilitates exclusion of drug utilization from Part D coverage.

(b) The assistance is provided during the whole coverage year (or the remainder of the year, if the beneficiary qualifies mid-year).

(c) Assistance is available, even if the beneficiary's need is periodic.

(d) PAP's assistance is accurately documented and capable of verification.

(e) Assistance is rendered based on reasonable and uniform measures of financial need.

(f) The arrangement complies with any guidance from CMS.

(iii) Assistance does not count towards TrOOP.

c. *"Coalition Model" PAP*.

(i) **Structure**. Multiple manufacturers form a jointly-administered PAP.

(ii) **Desirable characteristics**.

(a) Safeguards are included to avoid incentives for beneficiaries to favor one drug product, or one or more service providers or suppliers.

(b) The program includes a large number of manufacturers, including competing manufacturers.

(c) All of each participating manufacturer's products are included in the PAP.

(d) Ideally, the beneficiary retains some coinsurance obligation.

d. *Bulk replacement model*.

(i) **Structure**. Manufacturer provides free drugs to clinics, hospitals, or other entities that treat uninsured or indigent patients.

(ii) **Desirable characteristics**.

(a) Safeguards are included that protect beneficiaries from being steered to particular drugs based on the interests of their service providers or suppliers.

(b) Federal programmatic costs do not increase.

(c) Drugs are not charged to Federal healthcare programs.

(d) Drugs should be distributed to patients based on reasonable and consistent financial need criteria.

(e) Donated drugs do not vary with the value or volume of the receiving entity's referrals to the manufacturer.

(f) Manufacturers may receive an accounting of the use of their drugs, without patient names.

2. *Advisory Opinions*. Multiple advisory opinions reiterate the OIG PAP Guidance requirements, as applied to individual circumstances. Some

advisory opinions, however, address more unique arrangements, such as the following:

a. *Advisory Opinion 12-02*. Coupons for discounts on healthcare services offered via a website considered acceptable because: (a) discount applies to whole amount, and not just the patient portion; and (b) the customers and sellers would comply with the discount safe harbor.

b. *Advisory Opinion 08-04*. Drugs furnished at no charge on a trial basis considered to be acceptable because: (a) the drugs were not charged to any Federal healthcare program; (b) the patients were not required to continue using the product after the trial period; (c) the product at issue is not susceptible to overutilization; and (d) other safeguards exist, such as acknowledgement by the physician that the drug is being received free of charge and that manufacturer and physician are in compliance with the PDMA.

D. State laws. Beyond laws governing Federal healthcare programs, there are also State laws, which sometimes reach to all residents of a State. One example of these laws is Massachusetts, which broadly attaches criminal penalties to furnishing anything of value to any person to induce the purchase of an item reimbursable under insurance. Thus, PAP coinsurance subsidies to insured individuals could implicate this statute.

II. Privacy & Security Laws

A. HIPAA. HIPAA ensures that protected health information is kept private and secure.

1. If a manufacturer were considered a "covered entity" under HIPAA because of its reimbursement support activities, then it would have certain obligations:

a. The manufacturer would need to develop policies and procedures for implementing HIPAA.

b. The manufacturer's workforce would need to be trained regarding HIPAA requirements.

c. The manufacturer would need to hire a chief privacy officer.

d. It would need to furnish beneficiaries with a notice of privacy practices, and it would need to make efforts to secure an acknowledgement of receipt of the notice from beneficiaries.

e. The manufacturer would need to provide an accounting to beneficiaries seeking information regarding the use of their

protected health information, and would need to amend their records under certain circumstances.

f. The manufacturer would need to provide certain administrative, technical, and physical safeguards for beneficiary protected health information.

2. Types of "covered entities."

a. Health care providers that conduct certain transactions in electronic form.

(i) A health care provider is an entity that furnishes, bills, or receives payment for health care. Health care includes the sale or dispensing of a drug or device.

(ii) Covered transactions include seeking payment in an electronic form, determining a patient's eligibility for coverage electronically, seeking an electronic authorization, or determining the status of a claim electronically.

b. Health care clearinghouses.

(i) Entities that convert claims in nonstandard format into standard format.

c. Health plans.

(i) Entities that finance healthcare through the issuance of insurance or otherwise.

B. FTC Act. FTC has entered into enforcement actions against companies that retroactively change their privacy practices that have been put on their website, on the basis that such action constitutes a deceptive trade practice. To the extent that a manufacturer disseminates its privacy policies to patient receiving reimbursement support services, it must adhere to those policies, or face possible action by FTC.

III. **Medicaid Drug Rebate Program**.

A. Background. Medicaid drug rebates for an innovator drug are calculated by multiplying Medicaid utilization for a given State by the difference between average manufacturer price ("AMP") and the manufacturer's "best price" (or, if more, 23.1%). AMP and best price are determined by examining a manufacturer's sales data during the quarter at issue. Depending upon the structure of the price concession to the consumer, the sale to a consumer could

impact the amount of the rebate. CMS allows, however, certain price concessions to consumers to be excluded from the drug rebate calculation.

B. Prior Requirements. CMS published a final rule in July, 2007 implementing 2006 changes to the Medicaid Drug Rebate Statute. However, CMS withdrew portions of this rule in November, 2010. It is not entirely clear which portions of this rule remain in effect. In the July, 2007 rule, CMS specified criteria as to when PAP assistance is excluded from consideration in determining a product's AMP and best price. Possibly, this guidance remains in effect at this time. The criteria include that:

1. The drugs are given for free without any purchase requirement, or assistance is based on the financial need of low income individuals and families.

2. The amount of the subsidy is determined by a manufacturer, without negotiation with any third party.

3. The entire amount of the free product or subsidy is made available to the individual patient, without any portion of the benefit being conferred on a third party, such as a retail pharmacy.

4. The pharmacy collects either no additional payment, or only a bona fide service fee.

Additionally, the provision of free goods without any contingencies separately qualifies for exclusion from best price.

C. Proposed Requirements. In February, 2012, CMS issued new proposed rules governing the Medicaid Drug Rebate Program. CMS has stated that, so long as the pharmacy does not receive a discount, copayment assistance programs that "provide free goods that are not contingent on future patients" would be excluded from AMP and best price. Commenters have pointed out to CMS that copayment assistance programs do not provide "free goods" to beneficiaries, but rather they provide financial assistance. It is unclear whether CMS will, in light of these comments, revise its proposal in its final rule.