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PHARMACY BENEFITS MANAGEMENT UPDATE

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ABOUT US

The Phoenix Law Group of Feldman Brown Wala Hall and Agena, PLC is one of the few law firms in the country with an entire practice group devoted exclusively to pharmacy benefits and operations. What sets our practice group apart? For starters, it is made up entirely of attorneys that have in-house counsel experience, giving us significant expertise in an extremely complex industry.

Update on Manufacturer Copay Cards

Over the years, pharmaceutical manufacturers have tried different methods to convince consumers to select their brand-name drug over competitor's drugs or even over available generic drugs. Some of these methods have included offering free samples, coupons, and, most recently, co-pay cards. Co-pay cards are designed to encourage a consumer to purchase the manufacturer's drug product by providing the consumer with a card or voucher that when presented at the pharmacy will cover all or part of the consumer's co-payment for that drug product. Thus, if a consumer has a choice of paying a $25 copay for a brand name drug or a $5 copay for the corresponding generic drug, and the manufacturer has provided the consumer with a $25 copay card, then the consumer actually faces the choice of purchasing the brand name for no money out of the consumer's pocket, or paying $5 to purchase the generic. In this way, pharmaceutical manufacturers have been successful in increasing their market share and, they say, increasing patient adherence to prescribed drug therapy and thus lowering overall healthcare costs through better outcomes. However, opponents assert that copay cards actually increase health care costs by undermining health plans' tiered copay formularies.

Health benefit plans often rely on tiered-cost sharing to align the interests of patients, health care providers, and health benefit plans. Without cost-sharing provisions, patients and physicians choosing prescription drugs have little or no incentive to choose less costly drugs. Thus, cost-sharing has a primary purpose of imposing a personal financial obligation on the covered individual in order to encourage price sensitivity and achieve the range of acceptable balance between coverage and cost.

The Federal Anti-Kickback Act, of course, prohibits offering or paying any remuneration to induce a person to purchase any item for which payment may be made in whole or in part under a Federal health care program[i]; and the Massachusetts False Health Care Claims Actprohibits offering or paying any remuneration to induce any person to purchase any item for which payment is or may be made in whole or in part by a health care insurer.[ii]In order to avoid violating these statutes, copay cards virtually always include disclaimers on them stating that persons covered by Medicare or Medicaid, or located in the State of Massachusetts, are not eligible to participate in the program.

Recently, there have been several actions taken that may result in significant changes to manufacturer copay programs:

- In March of 2012, several union plans filed a series of proposed class action lawsuits against eight large drug manufacturers charging them with unlawful prescription co-payment subsidy programs. The lawsuits were filed by the AFSCME District Council 37 Health & Security Plan Trust, Sergeants Benevolent Association, the New England Carpenters, and the Plumbers and Pipefitters Local 572 Health and Welfare Fund. The targeted drug manufacturers are: Abbot Laboratories, Amgen, AstraZeneca, Bristol-Meyers-Squibb, GlaxoSmithKline, Merck, Novartis, and Pfizer. The lawsuits allege two bases for the defendants' liability: (i) federal racketeering laws, and (ii) federal antitrust laws. Applying the federal racketeering laws, the plaintiffs allege that the defendants' routine waiver of co-payments means that the true costs for reimbursement of the routinely subsidized drug are less than represented by the drug manufacturer and pharmacy, and thus the amount of reimbursement imposed on the health benefit plan is inflated and is prohibited as a form of insurance fraud. Applying the antitrust laws, the

Primarily representing pharmacy benefit managers (PBMs) and health plans, we work with our clients daily as an extension of their in-house legal departments. Because we get to know our clients thoroughly, we understand how to achieve their business goals, and are able to provide each with pragmatic advice and workable solutions. From contract development and negotiation, to structuring operations to meet regulatory requirements, our experience allows us to handle a client's needs seamlessly without wasted time getting up to speed.

plaintiffs allege that under Section 2(c) of the Robinson-Patman Act, a seller cannot lawfully pay undisclosed kickbacks to someone who makes a decision to purchase a product that is paid for by another (15 USC § 13(c)). The suits seek damages under 18 USC § 1964(c) for violations of the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 USC §§ 1962 (c) and (d); and under Section 4 of the Clayton Act (15 USC § 15) for overpayments caused by the defendants' undisclosed kickbacks.

- On April 20, 2012, the US Department of Justice announced that it had reached a settlement with Walgreens pharmacy chain under which Walgreens paid $7.9 million to resolve allegations that Walgreens violated the False Claims Act. The settlement resolved allegations that Walgreens offered illegal inducements to beneficiaries of government health care programs, including Medicare, Medicaid, TRICARE and the Federal Employees Health Benefits Program (FEHBP), in the form of gift cards, gift checks and other similar promotions that are prohibited by law, to transfer their prescriptions to Walgreens pharmacies. Although Walgreens placed disclaimers on the coupons stating that the offer was not valid with Medicaid, Medicare or any other government program, the government alleged that Walgreens employees frequently ignored the stated exemptions on the face of the coupons and handed gift cards to customers who were beneficiaries of government health programs, in violation of federal law. Thus, although these allegations did not involve manufacturer copay cards, they suggest that the government does not view simply stating program exclusions on the coupon or copay card as being sufficient to avoid violating the False Claims Act or Federal Anti-Kickback Statute.
- The Patient Protection and Affordance Care Act added four new exceptions to the beneficiary inducement prohibition set forth in 42 USC § 1320a-7a(a)(5). In particular, one of these new exceptions provides that the term "remuneration" does not include: "the offer or transfer of items or services for free or less than fair market value by a person, if- (i) the items or services consist of coupons, rebates, or other rewards from a retailer; (ii) the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and (iii) the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under title XVIII or a State health care program (as defined in section 1128(h))." Of note is that the exception refers to coupons, rebates, or other rewards "from a retailer." Although it would be difficult to argue that a manufacturer constitutes a "retailer," some have questioned whether a manufacturer coupon (or copay card) offered by a retail pharmacy, could be construed to fit within this exception. Also, this exception does not modify the anti-kickback prohibition referenced above and set forth in 42 USC § 1320a-7b(b)(2).
- On May 1, 2012, the Office of the Inspector General (OIG) issued an Advisory Opinion concluding that a loyalty card issued by a retail pharmacy and entitling the customer to apply out-of-pocket amounts paid for prescription purchases at the pharmacy (including deductibles and co-payments on Federally reimbursable prescription items)towards earning discounts on gasoline purchases: (i) would not constitute grounds for the imposition of civil monetary penalties under 42 USC §1320a-7a(a)(5); and (ii) although the proposed arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administration sanctions under 42 USC § 1320a-7b(b)(2). In reaching this decision, the OIG referenced the following points as being significant: (i) the requestor operated supermarkets and pharmacies that sell items directly to the public and the rewards consisted of coupons, rebates, or other rewards from a retailer; (ii) the loyalty card program would be offered on equal terms to all customers at the requestor's supermarkets and pharmacies; and (iii) customers could redeem rewards only on their purchase of gasoline, which is not an item or service for which a beneficiary could be reimbursed in whole or in part by Medicare or Medicaid programs (thus there would be no tie to Federally reimbursable items on the "redeeming" side of the transaction). With respect to its analysis of the anti-kickback statute, the OIG found it significant that there would be no specific incentive (i.e., no "bonus" rewards) for transferring prescriptions to the requestor's pharmacies and that the proposed arrangement would not involve a waiver or reduction in any cost-sharing amounts; only the amounts actually paid out-of-pocket by a customer would count toward earning rewards. Thus, the OIG did not give any indication that it would be willing to apply the retailer coupon exception of the beneficiary inducement prohibition discussed

above to manufacturer coupons, and in fact, seemed to suggest that it would not look favorable upon such an arrangement.

- The Massachusetts House is considering lifting a ban on drug-maker issued copay cards. The House voted to lift the ban last session but the effort died in conference committee talks with the Senate. Re. David Sullivan (D-Fall River), who has filed the bill several times, said after an October hearing on the issue that he thinks it will finally pass this session. The bill (H 2383), which has more than 30 co-sponsors, was heard by the Joint Committee on Public Health on October 4. The Public Health Committee discharged the bill to the Joint Committee on Health Care Financing in March.

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[i] 42 USC § 1320a-7b(b)(2).
[ii]Mass. Gen. Laws ch. 175H § 3.

For the second year in a row, the Phoenix Business Journal has named The Phoenix Law Group Of Feldman Brown Wala Hall & Agena to the list of largest specialty firms in Phoenix for its Pharmacy Benefits and Operations practice.

For additional information that impacts the pharmaceutical benefit industry, visit PLGTRACK.COM or contact Samantha Brown (sbrown@phoenixlawgroup.com), Laurel Wala (lwala@phoenixlawgroup.com), or Cami Agena (cagena@phoenixlawgroup.com) at The Phoenix Law Group (www.phoenixlawgroup.com).