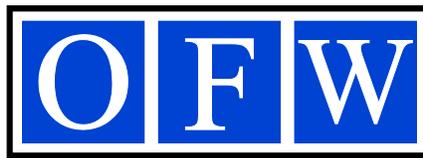


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**MEMORANDUM**

October 9, 2013

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**BY ELECTRONIC MAIL**

**TO:** Cathy Polley, R.Ph.  
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**FROM:** Olsson Frank Weeda Terman Matz PC

**RE:** Points To Consider In Offering Pharmacy Rewards Programs To Patients Covered Under Federal Government Insurance Programs

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This memorandum provides general points that supermarkets with retail pharmacy operations can consider when developing rewards programs that include patients who are covered under federal health care insurance programs. Concerned with potentially violating the federal anti-kickback statute and laws banning certain inducements to patients covered by Medicare, Medicaid, and other government programs, retailers have traditionally excluded from their rewards programs any patients whose prescriptions or other items or services are covered under federal health care insurance programs. Recent changes to federal law and Advisory Opinions issued by the Office of Inspector General (“OIG”) of the U.S. Department of Health and Human Services (“HHS”) now provide greater clarity regarding when a retail customer participating in federal government health care insurance programs may also participate in a retailer’s pharmacy rewards program. Below we review the relevant federal law and OIG opinions and discuss the elements a supermarket/pharmacy retailer may wish to consider in developing a rewards program that potentially includes its federally insured pharmacy patients.

## 1. BACKGROUND

### a. Federal Statutes

For purposes of this analysis, federal law imposes two separate limitations on rewards programs offered by retail supermarkets with pharmacy operations:

- Federal Anti-kickback Statute. This statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any “remuneration” to, in relevant part, induce or reward purchases of products (such as prescription drugs) reimbursable by a federal health care program (such as, primarily, Medicare, Medicaid, and TRICARE®). 42 U.S.C. § 1320a-7b(b). “Remuneration” is very broadly defined to include anything of value. *See, e.g.*, 67 Fed. Reg. 55,855, 55,856 (Aug. 30, 2002).
- Beneficiary Inducement Statute. This closely related statute, which is also called the civil monetary penalty statute, provides for monetary penalties and exclusion from federal programs for any person who offers or transfers “remuneration” to a Medicare or Medicaid beneficiary that is likely to influence the beneficiary’s selection of a reimbursable product (such as a prescription drug) or a provider of such a product (such as a retail pharmacy). 42 U.S.C. § 1320a-7a(a)(5). Again, remuneration is very broadly defined. *See, e.g.*, 67 Fed. Reg. at 55,856.
- Affordable Care Act. The 2010 health care reform legislation (“Affordable Care Act” or “ACA”) amended the definition of “remuneration” in the beneficiary inducement statute to expressly exclude certain retailer rewards. The effect of the amendment is to permit federal health care beneficiaries to receive retailer rewards if: (1) the reward consists of coupons, rebates, or other rewards from a retailer; (2) the rewards are made available on equal terms to the general public regardless of insurance status; and (3) the reward offer is not tied to the provision of other federally reimbursable goods or services. 42 U.S.C. § 1320a-7a(i)(6)(G).

### b. OIG Interpretations

OIG enforces the anti-kickback and the beneficiary inducement statutes and has issued guidance explaining the circumstances under which a retailer might offer rewards to its federally insured pharmacy patients without raising enforcement concerns.

**i. The \$10/\$50 Gift Exception**

OIG has interpreted the beneficiary inducement statute to allow health care providers (such as pharmacies) to offer patients with government insurance inexpensive gifts or services, defined as those having a retail value of no more than \$10 per item, and no more than \$50 in the aggregate annually per patient. 67 Fed. Reg. at 55,856; 65 Fed. Reg. 24,400, 24,410-411 (April 26, 2000). The only limitation of this exception is that the inexpensive gifts cannot be “cash” or “cash equivalents.” 67 Fed. Reg. at 55,856.

OIG has evaluated the \$10/\$50 gift exception in an Advisory Opinion (“Advisory Opinion” or “AO”). See [OIG AO No. 08-07 \(June 27, 2008\)](#). A health care system, which included hospitals, clinics, and other services, wished to put in place a program where it would offer a \$10 gift card to a patient who experienced a service shortfall, such as a long wait time or poor housekeeping. Gift cards would be offered for certain local vendors, such as restaurants and theater chains. OIG AO No. 08-07 at 2.

Key components of the program would include the following:

- These gift cards would not be redeemable for cash or for items or services provided by the health care system.
- The gift cards would not be redeemable at vendors of health care items and services that would be potentially reimbursable, such as pharmacies or durable medical equipment suppliers.
- The health care system would put in place a system to track the issuance of gift cards to patients to ensure that individual beneficiaries would not receive multiple cards having an aggregate value in excess of \$50 in one year.
- The gift card program would not be advertised.

*Id.*

Although the proposed program implicated both the beneficiary inducement statute and the anti-kickback statute, OIG nevertheless concluded that it would not impose sanctions under either law. As to the beneficiary inducement statute, OIG noted that the gift cards fell within the \$10/\$50 exemption for nominal gifts, assuming the health care system assured that individuals did not exceed the \$50 aggregate in one year. Further, the gift cards were “redeemable at specific vendors that did not sell items or services paid for by Federal health care programs” and were not “redeemable for cash or for items or services provided by the [health care system].”

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OIG AO No. 08-07 at 4. “In these circumstances, we conclude that the gift cards in the Proposed Arrangement will be nominal in value and will not constitute cash or cash equivalents.” *Id.* For these “same reasons,” OIG also concluded that it “would not impose ... administrative sanctions under the anti-kickback statute, in connection with the Proposed Arrangement.” *Id.*

In our view, the \$10/\$50 limits are the only “bright lines” in this area. *See* 67 Fed. Reg. at 55,856.

**ii. The ACA Retailer Rewards Exemption And OIG Advisory Opinion No. 12-05**

In [OIG AO No. 12-05](#) issued in 2012, OIG interpreted the ACA statutory exception, 42 U.S.C. § 1320a-7a(i)(6)(G), to the definition of prohibited “remuneration” in connection with a loyalty card rewards program of a supermarket and pharmacy chain. Under the proposed program, customers would earn discounts on gasoline purchases at participating gas stations, based on the amount of the “allowable purchases” at the chain’s supermarkets and retail pharmacies.

Specifically, for every \$50 that a customer spent in the supermarkets and pharmacies, the customer was entitled to a 10 cent per gallon discount on a single purchase of gasoline, up to a maximum of 20 gallons, at participating gas stations. The maximum savings a customer could receive under the program was 4% of that individual’s total allowable purchases. The program did not provide for additional bonuses for transferring prescriptions, and dollars spent on prescription drug cost-sharing did not generate higher or different rewards than dollars spent on other purchases. The portion of a prescription drug paid for by federal or private insurance would not be taken into account in determining eligibility for rewards.<sup>1</sup> OIG AO No. 12-05 at 2-3 and n. 3.

The question posed to OIG was whether a federally insured patient’s out-of-pocket costs (such as the deductibles and co-payments) on prescription items could be included in the “allowable purchases” the patient accrued for purposes of earning gas rewards. OIG concluded that the loyalty card gas reward accrued on out-of-pocket expenses paid under a federal prescription drug program (1) satisfied the exception to the definition of “remuneration” under the ACA amendment to the beneficiary inducement statute, and (2) posed a low risk of fraud and abuse under the anti-kickback statute.

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<sup>1</sup> [OIG AO No. 12-14](#), also issued in 2012, addressed a very similar gasoline rewards program, with the difference that the maximum savings a customer could receive was smaller. OIG’s reasoning in both advisory opinions was identical, and essentially verbatim. OIG AO No. 12-14 appears to be an example of a “me too” advisory opinion, discussed later in this memorandum.

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OIG first analyzed the proposed gas rewards program under the beneficiary inducement statute. OIG assumed that, given the cumulative nature of the gasoline rewards, many customers could exceed the \$10 per item, or \$50 annual gift limit. OIG AO No. 12-05 at 5.<sup>2</sup> OIG then concluded that, although the retail gas rewards might be more than nominal in value, they nevertheless met the three criteria under the ACA applicable to retailer rewards and would not constitute unlawful “remuneration.”

OIG found the first two ACA criteria were met because the reward program would be offered by a retailer – a supermarket chain with in-store pharmacies – and would be offered on equal terms to all customers. *See* 42 U.S.C. § 1320a-7a(i)(6)(G)(i)-(ii); OIG AO No. 12-05 at 5. The third ACA criterion was met as well. OIG concluded that the offer or transfer of the gas rewards would not be tied to the provision of reimbursable goods or services. *See* 42 U.S.C. § 1320a-7a(i)(6)(G)(iii). Because customers could redeem awards only on their purchases of gasoline, which is not reimbursable by the Medicare or Medicaid programs, there would be no tie to federally reimbursable items on the “redeeming” side of the transaction. OIG also found that there would be no tie with federal insurance programs on the “earning” side of the rewards transaction. Importantly, although the rewards program would allow federal health care program beneficiaries the opportunity to include their out-of-pocket prescription costs together with the rest of their in-store spending to earn rewards, prescription purchases were not required and were not treated any differently than any other purchase in the supermarket and pharmacy chain. OIG AO No. 12-05 at 5.<sup>3</sup>

OIG then evaluated the proposed gas rewards program under the anti-kickback statute. OIG noted at the outset that ACA’s statutory exception to the definition of remuneration applies only to the beneficiary inducement statute, not the anti-kickback statute. Nevertheless, OIG concluded that the proposed arrangement also would not be of concern under the anti-kickback statute. OIG concluded that the risk that the proposed arrangement would steer Medicare and Medicaid beneficiaries to requestor’s stores was low because the majority of requestor’s stores are general supermarkets that sell a broad range of non-prescription items. In addition, there would be no “bonus” reward for transferring prescriptions to requestor’s pharmacies. OIG AO No. 12-05 at 6. OIG also stated that the proposed arrangement would be unlikely to result in

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<sup>2</sup> For example, if a consumer had accrued \$400 in allowable purchases, he or she would receive 80 cents off per gallon of gas, up to 20 gallons, or \$16.

<sup>3</sup> We note that the OIG analysis is somewhat inartful here in that it concludes that rewards would not be “tied” to federal insurance programs even though rewards could accrue on a customer’s out-of-pocket expenses incurred when purchasing prescription drugs reimbursable under federal health care programs.

overutilization,<sup>4</sup> because any cost sharing amounts paid by customers that would count towards their rewards would result from prescription drugs already prescribed. *Id.* OIG characterized the rewards as “modest.” *Id.*

## **2. EVALUATION OF HYPOTHETICAL REWARDS PROGRAMS**

In this section, we provide our comments on some hypothetical features of retailer rewards programs that seek to include beneficiaries under federal health care insurance programs. Our comments below address two possible provisions under which these programs may proceed: (1) the \$10/\$50 exception; and (2) the parameters of the ACA exemption for retailer rewards as interpreted by OIG AO No. 12-05.

Any contemplated rewards program should be evaluated separately under both sets of criteria. A program that does not appear to be within the scope of the \$10/\$50 exception may nevertheless be within the parameters of OIG AO No. 12-05, or vice-versa. If a particular reward program appears to be “acceptable” under *either* the \$10/\$50 exception *or* under OIG AO No. 12-05, the sponsoring supermarket and pharmacy likely would have a basis for moving forward. As explained more fully in sections 4 and 5 below regarding the limitations of this memorandum, we caution that developing a compliant pharmacy rewards program is complex, highly fact specific, and requires careful legal analysis beyond the scope presented here.

### **a. The \$10/\$50 Gift Exception**

As discussed, OIG permits gifts if not more than \$10 per item and \$50 in the aggregate annually per patient, under some circumstances. The following are points to consider in developing a rewards program that contemplates using this exception for beneficiaries under federal health care insurance programs.

- **Is the reward a “cash equivalent”?** To be within the four corners of the \$10/\$50 exception, the reward cannot be “cash” or a “cash equivalent.” Although OIG has not defined “cash equivalent,” in OIG AO No. 08-07, OIG determined that a \$10 gift card was not a “cash equivalent.” *See* OIG AO No. 08-07 at 4. On this basis, it would seem that OIG would consider a general merchandise credit

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<sup>4</sup> Whether a proposed arrangement would encourage overutilization of reimbursed items or services is an important component of the OIG’s anti-kickback analysis. *See, e.g.*, 64 Fed. Reg. 63,518 (Nov. 19, 1999); 56 Fed. Reg. 35,952 (July 29, 1991).

or other similar reward to not be an impermissible “cash equivalent” if it cannot be redeemed for cash.

- **\$10 Individual Limit.** An individual reward may not be more than \$10. Assuming the total maximum value of each individual item award is \$10 or less, the reward is within the \$10 prong of the \$10/\$50 reward limitation.
- **\$50 Annual Aggregate.** The total rewards paid to a patient in a year must not exceed \$50 in one year. Assessing compliance with the \$50 annual aggregate reward per patient may be challenging for a retailer. Depending on the program details and the likelihood that any individual with federal benefits could accrue more than \$50 in rewards per year, a retailer may want to establish a tracking system to limit the amount of awards that can be earned in any given year. We note that there is no “requirement” to establish a tracking system. However, if the \$50 annual aggregate limit is exceeded, the exception would no longer be available, even if each individual transaction was no more than \$10.
- **Goods and services for which the reward may be expended.** In AO No. 08-07, OIG specifically noted that the \$10 gift cards that the health care system would provide to patients under the proposed program were for restaurants and entertainment, and not for vendors that sold goods or services paid for by federal health care programs. The Advisory Opinion also stated that no gift card could be used to pay for goods or services within the health care system itself. Using gifts for potentially reimbursable goods or services, such as flu shots, health screenings, or durable medical goods, is outside the scope of OIG AO No. 08-07 and is potentially a concern.

Rewards program features that do not appear to qualify under the \$10/\$50 exception should also be evaluated with regard to the parameters of the ACA retailer rewards exemption as interpreted by OIG Advisory Opinion No. 12-05, discussed in the next subsection below.

**b. Reliance Upon The ACA Retailer Rewards Exemption And OIG Advisory Opinion No. 12-05**

In Advisory Opinion No. 12-05, OIG applies the ACA retailer rewards exemption, 42 U.S.C. § 1320a-7a(i)(6)(G), and sets forth the elements of a rewards program a retailer

offered to its federally insured pharmacy customers that complied with the beneficiary inducement statute and did not raise enforcement concerns under the anti-kickback statute. Below are points to consider in developing a rewards program including federal beneficiaries that relies upon the ACA retail rewards exemption and OIG AO No. 12-05.

- **Any rewards program must comport with the ACA's amended definition of exempt remuneration.** Pursuant to 42 U.S.C. § 1320a-7a(i)(6)(G) and OIG AO 12-05:
  1. The rewards program is offered by a retailer that sells items directly to the public and allows customers to earn rewards for their allowable purchases in the stores.
  2. The retailer offers the rewards on equal terms to all customers.
  3. The rewards are not tied to the provision of other items or services reimbursed in whole or in part by federal health care programs.
  
- **Allowable purchases on which rewards accrue include both regular store and pharmacy merchandise and a federally insured patient's out-of-pocket costs on prescription items.** This reward does not appear to be objectionable under OIG AO No. 12-05. In OIG AO No. 12-05, OIG concluded that loyalty card gas rewards could accrue on a patient's out-of-pocket expenses paid under a federal prescription drug program because the reward satisfied the exception to the definition of "remuneration" under the beneficiary inducement statute, and posed a low risk of fraud and abuse under the anti-kickback statute.
  
- **Rewards are redeemable for general merchandise (i.e., merchandise not reimbursable under federal health care insurance programs) at the retailer's own supermarkets or pharmacies.** This reward feature does not appear to be objectionable. Although the gasoline rewards reviewed by OIG in AO No. 12-05 could only be redeemed at gas stations not operated by the supermarket/pharmacy, nothing in the Advisory Opinion suggests that this factor affected OIG's conclusion. Rather, 42 U.S.C. § 1320a-7a(i)(6)(G) and OIG AO No. 12-05 require that the reward not be tied to the provision of reimbursable items or services. So long as this requirement is met, it does not appear to make a difference whether the reward is redeemable at the issuing

supermarket or pharmacy, or only at an unrelated retail establishment, such as a gas station. Moreover, we cannot think of any policy reason why OIG would consider this difference meaningful.

- **Rewards may be more valuable than the scenario addressed by OIG in Advisory Opinion No. 12-05.** OIG characterized the rewards it addressed – which have a maximum value of 4% of the customer’s total allowable purchases (10 cents off every gallon for every \$50 in allowable purchases and up to 20 gallons total in a single gas purchase), as “modest.” OIG AO No. 12-05 at 6. OIG characterizes gifts of \$10 (\$50 annually per person) as nominal in value and recognized that the gas rewards could exceed these sums. OIG AO 12-05 at 5. As the gasoline rewards were potentially more than “nominal,” but still “modest,” their value did not appear to have been an important factor in OIG’s analysis. We believe that OIG’s concerns could increase as the value of the rewards increases.
- **Rewards accrue based on the number of prescriptions filled (e.g., one reward earned for every six prescriptions filled).** This program feature appears to be outside the parameters of OIG AO No. 12-05 and so is a potential concern. In OIG AO 12-05, OIG noted favorably that patients were not required to purchase prescription drugs in order to earn rewards under the proposed program. OIG AO No. 12-05 at 5-6. Requiring that rewards be earned through prescription purchases may impermissibly “tie” the provision of reimbursable prescription drugs to the earning of the reward, which would not comport with 42 U.S.C. § 1320a-7a(i)(6)(G)(iii). Additionally, earning rewards solely by filling prescriptions reimbursed under federal health care programs could be a significant concern to OIG as it may believe such a program could increase program utilization, which is a factor OIG considers in whether a proposed arrangement violates the anti-kickback statute. *See, e.g.,* [OIG AO No. 13-03](#) (OIG explaining that proposed arrangement could lead to overutilization of reimbursable services and increased cost to federal health care programs).

- **Special incentives are provided for transferring a prescription to the pharmacy (e.g., additional “credit” in determining eligibility for the reward and/or a “bonus” reward).** OIG specifically noted that the gasoline rewards program it reviewed did not provide incentives or “bonus” rewards for transferring prescriptions to the Requestor’s pharmacies. *See* OIG AO No. 12-05 at 5 and 6. As described in more detail in section 3 below, in April 2012, OIG entered into a settlement with a pharmacy chain that provided \$25 gift cards to encourage patients to transfer their prescriptions to the chain’s pharmacies. Though the program rules excluded beneficiaries under federal health programs, pharmacy employees routinely ignored the exclusion. *See* [U.S. Department of Justice Press Release, April 20, 2012](#). Thus, providing incentives in the form of rewards or bonus rewards for transferring a prescription to the store pharmacy are outside the parameters of the Advisory Opinion and are potentially a significant enforcement concern.
- **Additional “credit” is available in connection with filling a prescription (e.g., twice as much dollar credit for prescriptions as for general merchandise purchases).** This program feature is outside the parameters of the Advisory Opinion and so is a potential concern. One of the factors upon which OIG relied was the fact that prescription purchases were not treated any differently from other purchases for purposes of earning rewards. *See* OIG AO No. 12-05 at 5 and 6. Offering a bonus reward on prescription purchases may impermissibly “tie” the provision of reimbursable prescription drugs to the earning of the reward, which would not comport with 42 U.S.C. § 1320a-7a(i)(6)(G)(iii).
- **Rewards are, in whole or in part, applied as savings on goods or services potentially reimbursable by government insurance (e.g., savings on health screenings or flu shots offered by the pharmacy).** This program feature is outside the Advisory Opinion and so is a potential concern. In OIG AO 12-05, customers could redeem rewards only for gasoline, which is not reimbursable under federal health care programs and so there was no impermissible tie between the reward and reimbursable goods or services. *See* OIG AO No. 12-05 at 5; 42 U.S.C. § 1320a-7a(i)(6)(G)(iii).

Rewards program features that do not appear to be within the parameters of OIG Advisory Opinion No. 12-05 should nevertheless be evaluated under the \$10/\$50 gift exception, discussed above.

### **3. EVALUATING OIG ENFORCEMENT RISK IN PHARAMCY REWARDS PROGRAMS**

In the preceding discussion, we have provided our general thinking on a number of elements that could be part of a supermarket pharmacy rewards program that includes federal health care insurance plan beneficiaries. A particular contemplated practice is not necessarily of enforcement concern to OIG because it does not fall under the \$10/\$50 exception, the ACA exception, or the Advisory Opinions that interpret these exceptions.

OIG does actively monitor pharmacy activities and has shown it is particularly concerned with coupon, rebate, and rewards programs that compensate government beneficiaries for transferring their prescriptions. In fiscal year 2012, OIG resolved four cases against pharmacies. Three cases involved outright fraud, submission of false claims for reimbursement, and other criminal conduct. A fourth case is, as discussed below, significant to pharmacy rewards programs. *See* [The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2012](#).

In April 2012, Walgreens paid the United States and participating states \$7.9 million to resolve allegations that the pharmacy chain violated the federal False Claims Act, the anti-kickback statute, and the beneficiary inducement statute. The investigation found that Walgreens had offered government health care beneficiaries \$25 gift cards when they transferred a prescription from another pharmacy to Walgreens. Although the company's advertisements typically acknowledged that the offer was not valid with any government insurance program, Walgreens employees frequently ignored the exemption and gave gift cards to plan beneficiaries. *See Id.* at 25-26.

According to publicly available information, OIG has also been investigating at least one other major pharmacy regarding allegations that federal health care insurance beneficiaries were offered gift cards, cash, discounts or coupons to transfer their prescriptions to the chain's pharmacies.

Because there are few "bright lines" in this area, an FMI member developing a pharmacy rewards program should consult with its legal and regulatory advisors. A company's development of a rewards program should take into account relevant federal and state law and OIG guidance and Advisory Opinions, the overall enforcement environment, and the company's tolerance for risk.

#### **4. OIG ADVISORY OPINIONS AND THEIR LIMITATIONS**

In this memorandum, we have relied upon Advisory Opinions to describe how a pharmacy rewards program might lawfully include federal beneficiaries without triggering enforcement action under the beneficiary inducement statute, the ACA amendment to it, and the anti-kickback statute. However, OIG expressly limits the scope of its Advisory Opinions to the specific arrangement described; an Advisory Opinion is valid only for the entity who requested it and cannot be relied upon by any other individual or entity. *See, e.g.*, OIG AO No. 12-05 at 7 (“This advisory opinion is issued only to the Requestor. This advisory opinion has no application to, and cannot be relied upon, any other individual or entity.”)

Despite these express limitations, OIG Advisory Opinions are widely regarded as the best available insight into OIG’s current thinking and enforcement priorities. Thus, as a practical matter, a business arrangement permitted by OIG in an Advisory Opinion can be viewed as a type of informal “safe zone.” A business practice that is factually equivalent to or more conservative than that described in an Advisory Opinion is unlikely to be of concern to OIG. Each company must make its own business decision, in consultation with its legal counsel as appropriate, as to the extent to which the rationale of any Advisory Opinion can be applied to the company’s own operations.

A company may seek its own Advisory Opinion from OIG regarding its own proposed program. Details regarding the process are available [here](#). Where a company closely follows an existing OIG Advisory Opinion, obtaining a favorable opinion from the OIG for the company’s own program can provide business advantages and regulatory comfort. For example, AO No. 12-14 appears to be a “me too” opinion based on AO No. 12-05. *See* note 1, *supra*.

Seeking an Advisory Opinions based on new circumstances not previously addressed by OIG, however, can be risky. OIG’s Advisory Opinion decisionmaking process is not transparent and can be unpredictable. From January 1, 2012 through August 30, 2013, OIG concluded that about 10% of the proposed arrangements it reviewed would pose enforcement concerns. Having a “negative” Advisory Opinion could certainly have an adverse effect on business negotiations regarding the proposed arrangement, and could prevent a company from proceeding with a contemplated program in “good faith.” Thus, the decision to proceed with requesting an Advisory Opinion for a scenario not previously addressed by OIG must be made carefully and in consultation with experienced counsel.

#### **5. LIMITATIONS OF THIS MEMORANDUM**

This memorandum is for general informational purposes only to assist FMI members in general business decisionmaking. This memorandum is not intended to provide specific legal advice to FMI or to any of its members. Any FMI member that is contemplating a rewards

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program that takes into account patient co-payments for prescription products that are reimbursable, in whole or in part, by federally funded insurance programs should consult with its own legal and regulatory advisors about the specific details of its contemplated program.

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