Posted: April 8, 1998

[name and address redacted]

Re: Advisory Opinion No. 98-2

Dear [name redacted]:

We are writing in response to your request for an advisory opinion, in which you ask whether certain pharmaceutical discount pricing arrangements that are limited to arrangements between a manufacturer and wholesalers (the "Proposed Arrangement") will subject you to sanction under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), the exclusion authority related to kickbacks, section 1128(b)(7) of the Act, or the civil monetary penalty provision for kickbacks, section 1128A(a)(7) of the Act.

You have certified that all of the information you provided in your request, including all supplementary letters, is true and correct, and constitutes a complete description of the material facts regarding the Proposed Arrangement. In issuing this opinion, we have relied solely on the facts and information you presented to us. We have not undertaken any independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed, this opinion is without force and effect.

Based on the information provided and subject to certain conditions described below, we conclude that the Proposed Arrangement (as further defined below) would not constitute prohibited remuneration under the anti-kickback statute, section 1128B(b) of the Act, and would not constitute grounds for sanctions under sections 1128(b)(7) or 1128A(a)(7) of the Act. This opinion may not be relied on by any person other than the addressee and is further qualified as set out in Part III below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Company A proposes to enter into contracts with pharmaceutical wholesalers for the purchase of certain multi-source generic pharmaceuticals at a fixed percentage price reduction (the "Proposed Arrangement"). As part of the contractual arrangement, the wholesalers will provide limited promotional support for the purchased pharmaceuticals. The pharmaceutical wholesalers' customers include retail pharmacies, hospitals, and other health care providers that dispense the pharmaceuticals to patients pursuant to physician prescriptions. Some of these patients will be Federal program beneficiaries.[1] The Proposed Arrangement would generally be available to all pharmaceutical wholesalers willing to accept the terms offered by Company A. The wholesalers will not bill any Federal health care program. Rather, they will sell products to retail pharmacies, hospitals, and other health care providers that may, in turn, submit claims for program reimbursement.

The Proposed Arrangement pertains only to bioequivalent generic products that are available from more than one manufacturer, i.e. "multi-source generic products." Under the Proposed Arrangement, Company A would offer a wholesaler discount pricing on multi-source generic products that the wholesaler agrees to make its "preferred generic" for a given product line. The contracts between Company A and the wholesalers will specify the particular generic products that are "preferred generics" eligible for the price reduction to the wholesalers (the "Contracted Products").

Under the Proposed Arrangement, the amount of the price reduction, which would be paid in the form of quarterly rebates, would be calculated by taking the wholesaler's contracted product purchases, subtracting returns of Contracted Products, invoice

[1]The Medicare program generally does not cover self-administered outpatient prescription drugs, such as those sold by Company A. However, such drugs are typically covered by Medicaid, and may be covered by other Federal health care programs. Medicaid payments for covered drugs are usually made directly to the pharmacy, hospital, or other provider, although in some circumstances program reimbursement may be made to the patient. In addition, prescription drugs may be covered for Medicare beneficiaries enrolled in Medicare HMOs.

adjustments,[2] and chargebacks,[3] and multiplying the resulting amount by a fixed percentage. All purchases, returns, adjustments (if applicable), and chargebacks would occur within a single calendar quarter. The applicable fixed percentage would be set in advance pursuant to a written agreement with the wholesaler.[4]

A portion of the price reduction offered to certain wholesalers may be conditioned on the wholesalers' agreement to provide certain promotional support for the Contracted Products. These promotional activities are limited to the following:

- making informational phone calls to the wholesalers' retail customers regarding Contracted Products and special pricing on Contracted Products that may be available through the wholesaler;

- including Company A advertising materials relating to the Contracted Products in the wholesalers' mailings and deliveries to its customers;

- featuring advertisements for Contracted Products in the wholesalers' catalogs or other sales materials; and

- featuring the Contracted Products in the wholesalers' generic source catalog and trade show promotions.

In all cases, the promotional support contemplated by the Proposed Arrangement will relate exclusively to Contracted Products.

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[2]Adjustments include invoices priced incorrectly, discounts for prompt payment, and credits for inventory that may have decreased in price since the original purchase, i.e. floor stock adjustments.

[3]A chargeback is a sale to a Company A retail customer and is not considered a sale generated through the wholesaler's source program.

[4]The percentages for the Proposed Arrangement are disclosed in Company A's request for an advisory opinion. Because these numbers are potentially proprietary business information of Company A, we are not disclosing them here. We have, however, considered them in rendering our opinion. The portion of the price reduction attributable to wholesaler promotional activities will be no more than 25% of the total price reduction under the Proposed Arrangement.

Company A has represented that it will comply with all reporting requirements for pharmaceutical manufacturers under all Federal and state health care programs.[5] In particular, Company A will include any rebates paid under the Proposed Arrangement in its calculations of "average manufacturer price" or "best price" under the Medicaid drug rebate program. See 42 U.S.C. § 1396r-8. Under the Medicaid drug rebate program, in order for Medicaid payment to be available to states for a manufacturer's covered outpatient drugs, the manufacturer generally must have entered into and have in effect a rebate agreement with the Secretary, on behalf of the states, or with states directly, to the extent authorized by the Secretary. See 42 U.S.C. § 1396r-8a. Pursuant to these rebate agreements, a manufacturer must report its "average manufacturer price" and "best price", as defined in the statute. See 42 U.S.C. § 1396r-8b.

In addition, Company A has represented that:

- the Proposed Arrangement is not dependent on and does not operate in conjunction with (either explicitly or implicitly) any other arrangement or agreement between or among Company A, the wholesalers, any retail customers or providers, or any other party with respect to the Contracted Products.[6]

- Company A will (1) fully and accurately report the existence of the discount on the invoices, coupons, or statements submitted to the wholesalers; (2) inform the wholesalers in an effective manner that they may have obligations to report the discount; and (3) refrain from doing anything that would impede the wholesalers or the wholesalers' customers from meeting any obligations to report the discount. Contracts under the Proposed Arrangement between Company A and the wholesalers will contain a statement advising the wholesalers that they may have obligations

[5]This opinion is without force and effect if Company A fails to comply with all reporting requirements for pharmaceutical manufacturers under all Federal and state health care programs. We express no opinion about the manner or methods used by Company A to meet these reporting requirements.

[6]The Proposed Arrangement is the complete and entire arrangement that is the subject of this advisory opinion. The Proposed Arrangement may become illegal when considered in the context of other related conduct or arrangements. In such circumstances, this advisory opinion is without force and effect.

to report discounts accurately, including quarterly rebates, to appropriate Federal and state payors.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute, 42 U.S.C. §1320a-7b(b), makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce the referral of business covered by a Federal health care program. Specifically, the statute provides that:

> Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony.

42 U.S.C. § 1320a-7b(b). In other words, the statute prohibits payments made purposefully to induce referrals of business payable by a Federal health care program. The statute ascribes liability to both sides of an impermissible "kickback" transaction. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). “Remuneration” for purposes of the anti-kickback statute includes the transfer of anything of value, in cash or in kind, directly or indirectly, covertly or overtly.

The anti-kickback statute contains a statutory exception for “a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program.” 42 U.S.C. § 1320a-7b(b)(3)(A). Regulations implementing this discount “safe harbor” exception define the term “discount”, in relevant part, as:

> a reduction in the amount a seller charges a buyer (who buys either directly or through a wholesaler or group purchasing organization) for a good or service based on an arms-length transaction. The term *discount* may include a rebate check, credit or coupon directly redeemable from the seller only to the extent that such reductions in price are attributable to the original good or service that was purchased or furnished.

42 C.F.R. § 1001.952(h)(3). The regulation further provides that the definition of discount does not include "services provided in accordance with a personal or management services contract." Id.

The discount safe harbor regulations provide, in relevant part, that prohibited remuneration does not include a discount, as defined above, on a good or service received by a buyer "which submits a claim or request for payment for the good or service for which payment may be made in whole or in part under Medicare or a State health care program," provided certain other conditions described in the regulations are satisfied.[7] See 42 C.F.R. §1001.952(h). These additional requirements, imposed on both sellers and buyers, vary depending on how the buyers are reimbursed by the Medicare and Medicaid programs. Included among them are requirements that a discount be fully and accurately disclosed so that the benefit of the discount can inure to the Medicare and Medicaid programs, that a discount be for the specific good or service being purchased, and that discounts be earned in the same fiscal year as the purchase of the applicable good or service.

In 1994, we published certain proposed clarifications to the discount safe harbor. These clarifications included a proposal to define "rebate" for purposes of the regulations as "any discount which is not given at the time of sale." Accordingly, rebates would be covered by the safe harbor if offered to cost report buyers and capitated health plans under section 1876 of the Act, but would not be covered if offered to "other" buyers, because protected discounts to those buyers must be given at the time of the sale. The proposed clarifications also would make clear that a seller could receive safe harbor protection even if the buyer does not meet its obligations under the safe harbor, provided that the seller has acted in good faith and has not done anything that would impede the buyer from meeting its obligations.

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[7] See 42 C.F.R. § 1001.952(h)(1)-(3). In the preamble to the regulation, we explained that the statutory discount safe harbor "applies only to discounts obtained by health care providers who submit claims to the Medicare and Medicaid programs." 56 Fed. Reg. 35952, 35977 (July 29, 1991).

A further safe harbor regulation exists for personal services and management contracts. That safe harbor provides protection for written personal services contracts of at least one year's duration where (i) the services to be performed and, in certain circumstances, the schedule for performance are specified in the contract, and (ii) the aggregate amount of compensation is fixed in advance, based on fair market value in an arms-length transaction, and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made by Medicare or a state health care program. See 42 C.F.R. § 1001.952(d).

B. Analysis

For the reasons set out below, we conclude as follows:

- the Proposed Arrangement potentially is subject to the anti-kickback statute;
- the Proposed Arrangement does not qualify for either the discount or personal services contract "safe harbor"; but
- the Proposed Arrangement does not constitute prohibited remuneration for purposes of the anti-kickback statute.

First, the Proposed Arrangement is potentially implicated under the plain language of the anti-kickback statute, which prohibits the knowing and willful offer, payment, solicitation, or receipt of remuneration to induce a person to "arrange for or recommend purchasing, leasing, or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Here, the wholesalers will be offered remuneration in the form of a price reduction to induce them to purchase Contracted Products and to induce them to recommend or arrange for their customers to purchase such products from the wholesalers. Some of these customers may receive reimbursement under a Federal health care program.

Second, the Proposed Arrangement cannot fit into the discount "safe harbor". Strict compliance with all components of a safe harbor is necessary in order for a transaction to be protected by the safe harbor. In this case, the discount safe harbor only protects remuneration on a good or service received by a buyer that "submits a claim or request for payment for the good or service for which payment may be made in whole or in part under Medicare or a State health care program." 42 C.F.R. § 1001.952(h). Since Company A has represented that its wholesale customers will not submit claims or requests for payment to Medicare or Medicaid, the arrangement cannot qualify for the safe harbor.

Third, notwithstanding the unavailability of the safe harbor, the Proposed Arrangement does not constitute prohibited remuneration for purposes of the anti-kickback statute. We have previously observed that the discount exception to the anti-kickback statute manifests congressional intent to encourage price competition that benefits the Medicare and Medicaid programs. See 54 Fed. Reg. 3092 (January 23, 1989). Based on our review, the Proposed Arrangement furthers this legislative intent without otherwise posing a risk of program abuse.

As a threshold matter, the Proposed Arrangement is substantially similar to the arrangements protected by the current discount safe harbor. The discount under the Proposed Arrangement is applicable to specific transactions for specific products. Although the amount of the rebate to the wholesaler will not be known at the time of sale, the rebate will be available and accounted for by Company A in calculating its quarterly "average manufacturer price" or "best price" (depending on the product) for purposes of determining its Medicaid rebate. In sum, even though the wholesalers do not submit claims to Medicare or Medicaid for these purchases,[8] Company A's disclosures will ensure that the discounts are properly reported and reflected in the Medicaid rebate.

Under the Proposed Arrangement, the wholesaler may receive an additional price reduction on its purchases of Contracted Products for certain marketing activities directed at its retail customers. Historically, this Office has expressed concern about compensation for marketing activities based on a percentage of product sold; such arrangements can, in some circumstances, encourage overutilization or the inappropriate steering of Federal health care program business. We recognize that the portion of the price reduction conditioned on wholesaler marketing activities does not come within the personal services safe harbor, as the amount of compensation payable for those activities is neither fixed in advance nor unrelated to the volume or value of business generated for which payment may be made indirectly by a Federal health care program.

The Proposed Arrangement involves a discount on multi-source generic pharmaceutical products purchased by the wholesaler for its own account; in other words, the discount

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[8]Company A has represented that it will inform its wholesale customers that they may be required to report the discounts. Although there currently appear to be no reporting requirements for wholesale purchasers of pharmaceutical supplies that do not submit claims or requests for payment, Company A has represented that the prices charged for specific items under the Proposed Arrangement could be measured and fully reported to the appropriate Federal authorities, if such reporting were to be required.

is not a commission. Implicit in any manufacturer's discount to a wholesale purchaser is a financial incentive to the wholesale purchaser to increase its retail sales of the discounted product. That financial incentive does not change simply because the Proposed Arrangement conditions the discount on the performance of certain limited activities that directly support the resale of the Contracted Products. In such circumstances and in the context of generic drugs, there is little reason for disparate treatment between the Proposed Arrangement and a straightforward price reduction.[9]

C. Conclusion

For the above-stated reasons, we conclude that the Proposed Arrangement would not constitute prohibited remuneration under 42 U.S.C. § 1320a-7b(b).

We wish to make clear that the specific arrangement as approved in this advisory opinion may become illegal when considered in the context of other related conduct or arrangements. Moreover, this opinion letter is without force and effect if (1) any contract entered into under the Proposed Arrangement is dependent on or operates in conjunction with (either explicitly or implicitly) any other arrangement or agreement between Company A and the wholesaler with respect to Contracted Products; or (2) any contract entered into under the arrangement is dependent on or operates in conjunction with (either explicitly or implicitly) any other arrangement or agreement involving third parties (i.e. parties other than Company A or the wholesaler) with respect to Contracted Products.

III. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Company A, which is the Requestor of this opinion. This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a Requestor to this opinion.

[9]Nothing in this advisory opinion should be construed as suggesting that the same result would pertain for marketing services arrangements where the marketing agent is compensated by a commission based on a percentage of sales.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestor with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, and the arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, modify or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestor with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion.

Sincerely,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General