[Posted: November 10, 1998]

Dated: November 2, 1998

[names and addresses redacted]

Re: [names redacted]

Advisory Request No. 98-15

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion, in which you asked whether an arrangement for contracted pharmacy services between University A and Pharmacy Company B to facilitate an outpatient pharmacy program for the University's hemophilia center pursuant to section 340B of the Public Health Service Act (the "Proposed Arrangement") would constitute grounds for sanctions under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), the exclusion authority for 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.

Based on the facts certified in your request for an advisory opinion, we conclude that the Office of Inspector General ("OIG") will not subject the Proposed Arrangement, as described in the request and supplemental submissions, to sanctions arising under the anti-kickback statute pursuant to sections 1128(b)(7) or 1128A(a)(7) of the Act, provided that the compensation is fair market value as certified by the requesters.

This opinion may not be relied on by any persons other than the requesters of this advisory opinion and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Parties

Pharmacy Company B ("Company B") is a State X corporation in the business of providing home infusion therapies for a number of conditions, including hemophilia. In addition, Company B provides a range of related pharmaceutical services.

University A (the "University"), a State X not-for-profit corporation, operates a comprehensive hemophilia treatment center, for which it receives funding through the Maternal and Child Health Services Block Grant ("MCHB") program. The University provides care to residents of States X,

Y, and Z. The University does not have a pharmacy license and does not operate an in-house pharmacy.

B. The Section 340B Drug Discounting Program

Section 340B of the Public Health Service Act was enacted as part of the Veterans Health Care Act of 1992. Section 340B enables certain entities that typically serve a disproportionate number of uninsured and underinsured people to purchase certain drugs for outpatient treatment from drug manufacturers at greatly reduced prices. The entities that are eligible for the reduced prices -- defined in the statute as "covered entities" -- include comprehensive hemophilia diagnostic treatment centers receiving a grant under the MCHB program. Covered entities may only sell the drugs purchased under section 340B pricing to certain of their patients as defined in program guidance published in the Federal Register, 61 Fed. Reg. 55156 (Oct. 24, 1996). In response to a comment in a Federal Register notice regarding contracted pharmacy services guidelines, the Department of Health and Human Services (the "Department") noted that a modest drug markup does not appear inconsistent with the 340B program, if the savings resulting from the 340B discounts are used for purposes of the Federal program. See 61 Fed. Reg. 43548 (Aug. 23, 1996).

The discounted price under section 340B is calculated based on a formula that takes into account the Medicaid drug rebate manufacturers are required to pay to the states as a condition for payment under the Medicaid program. See 42 U.S.C. § 1396r-8.[(1)] Section 340B requires manufacturers of covered drugs to enter into pricing agreements with the Secretary of the Department. Covered entities enter into agreements with drug manufacturers to purchase covered drugs at or below the ceiling price established in the manufacturer's agreement with the Secretary and in section 340B(2).

Many covered entities do not operate an in-house pharmacy from which to dispense the drugs. To facilitate greater covered entity participation in the 340B program, the Health Resources and Services Administration ("HRSA") published guidelines and model contract terms for contracts between covered entities and pharmacy companies for pharmacy services agreements. See 61 Fed. Reg. 43549 (Aug. 23, 1996) (the "Guidelines"). The Guidelines provide a suggested format for such agreements, including the following terms:

(i) the covered entity will purchase the drug and assume responsibility for establishing its price;

(ii) a "ship to/bill to" procedure may be used in which the covered entity purchases the drug, and the manufacturer bills the entity for the drug, but ships the drug to the contract pharmacy;

(iii) the contract pharmacy will provide all pharmacy services (e.g., dispensing, record keeping, utilization review, patient profiling, counseling) and may provide other services (e.g., home care, reimbursement services);

(iv) the covered entity must inform its patients of their freedom to choose a pharmacy provider;

(v) section 340B prices are restricted to patients of the covered entity;

(vi) the contract pharmacy and the covered entity will adhere to all Federal, state, and local laws and requirements;

(vii) the contractor, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients;

(viii) the parties will not use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the contract pharmacy and the state Medicaid agency have established an arrangement to prevent duplicate discounting (see further discussion below); and

(ix) the parties understand that they are subject to audits by the Department and the participating manufacturers.

Because covered entities typically have patients who are Medicaid beneficiaries, the section 340B drug discounting program potentially subjects drug manufacturers to a risk of double discounting if the manufacturer pays a Medicaid drug rebate on a drug sold under 340B pricing. For example, if a drug purchased pursuant to section 340B were to be sold to a Medicaid patient and billed to a Medicaid program, the manufacturer could end up providing two discounts: (1) a discount at the time of sale due to the 340B price limits and (2) a discount in the form of the quarterly Medicaid rebate required of manufacturers under the Medicaid program. To prevent this result, section 340B provides that the dispensing of drugs purchased with a 340B discount must not result in the generation of a Medicaid rebate. Assuming this requirement is satisfied, covered entities may bill Medicaid for drugs purchased under section 340B pricing, although the amount charged to Medicaid may not exceed the 340B price plus a reasonable dispensing fee. See 58 Fed. Reg. 27293 (May 7, 1993), 58 Fed. Reg. 34058 (June 23, 1993). However, the Guidelines suggest that Medicaid prescriptions should not be filled with drugs purchased at 340B pricing, unless the contract pharmacy and the state Medicaid agency have established an arrangement to prevent duplicate discounting.[(2)]

In addition, covered entities that use a contract pharmacy may not be able to bill Medicaid for drugs purchased under the 340B drug discounting program because of the Medicaid prohibition on reassignment. Pursuant to the prohibition on reassignment, the entity that dispenses the drugs and provides related administrative services (i.e., the contract pharmacy) must be the entity that bills Medicaid.

C. The Proposed Arrangement

The complexities of section 340B drug discounting notwithstanding, the Proposed Arrangement itself is straightforward. The University, which the parties have represented is a covered entity for purposes of section 340B, desires to enter into a pharmacy services contract (the "Agreement") with Company B (i) to dispense anti-hemophilia factor (a covered outpatient drug) and other outpatient drugs prescribed by the University's hemophilia center for certain of its patients and (ii) to provide outpatient pharmacy services in connection with the 340B program for those patients, including, but not limited to, inventory management, billings, collections, and educational support. Company B's services will be available on an as-needed basis. The University selected Company B through a competitive procurement process. The Agreement is, and will be for its term, the only financial arrangement between the parties. In all respects material here, the Agreement complies with the Guidance issued by HRSA described above.[(3)]The compensation to be paid to Company B will be

calculated in accordance with a fee schedule attached to the Agreement. The fee schedule provides for Company B to be paid a fixed amount per unit of anti-hemophilia factor dispensed. The amount per unit drops if the volume dispensed exceeds a certain monthly threshold. The compensation may be renegotiated annually. The parties have represented that at all times the compensation will represent fair market value in an arms-length transaction for the services rendered.

To prevent duplicate discounting and to comply with the Medicaid prohibition on reassignment, the Agreement has been structured to exclude Medicaid fee-for-service patients from receiving drugs through the University's outpatient drug program.[(4)] Medicaid fee-for-service patients will be notified of this limitation in advance and will be informed that they must seek pharmaceutical services elsewhere. These patients may choose to seek such services directly from Company B or from another provider. All University patients (Medicaid and non-Medicaid) will be required to complete a patient choice form that lists alternate pharmacy services providers. The form states that the University and Company B have a financial relationship and requires the patient to acknowledge that he or she has selected a provider freely. Company B will segregate section 340B drugs purchased by the University from other pharmaceuticals and will maintain a tracking system capable of locating them.

II. LEGAL ANALYSIS

The anti-kickback statute makes it a criminal offense knowingly and wilfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce referrals of items or services paid for by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for 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 (3rd Cir.), cert. denied, 476 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. This Office may also initiate administrative proceedings to exclude persons from Federal health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.[(5)]

The Department has published safe harbor regulations that protect certain arrangements that might otherwise technically violate the anti-kickback statute from prosecution. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is only afforded to those arrangements that precisely meet all of the conditions set forth in the safe harbor. The regulatory safe harbor potentially applicable to the Proposed Arrangement is the personal services and management contracts safe harbor. See 42 C.F.R. § 1001.952(d). The Proposed Arrangement cannot qualify under this safe harbor, however, since, among other things,

the nature of the services provided under the Agreement preclude an exact specification of the schedule for their performance and the aggregate amount of compensation is not set in advance, as required by the regulation.

Nevertheless, arrangements that do not fit squarely within a safe harbor do not necessarily violate the anti-kickback statute. See, e.g., 56 Fed. Reg. 35952, 35954 (July 29, 1991). Such arrangements must be evaluated on a case-by-case basis. For the following reasons, we conclude that the Proposed Arrangement poses a minimal risk of fraud or abuse and would not be subject to OIG sanctions:

- The Proposed Arrangement implements the congressional intent embodied in section 340B and the HRSA Guidelines. The Proposed Arrangement enables the University's hemophilia center, which does not have access to an in-house pharmacy, to receive the benefits of the discounted drugs available under section 340B to hemophilia centers funded through the MCHB program. The Agreement comports in all aspects material to an inquiry under the anti-kickback statute with the Guidelines published by HRSA for entities seeking to comply with section 340B. The Guidelines make clear that the parties are responsible for complying with all Federal, state, and local laws and requirements, including the anti-kickback statute. The Guidelines also provide that the parties will be subject to governmental reporting and auditing requirements.

- Company B will be paid fair market value for services rendered. The only compensation Company B will receive under the Proposed Arrangement is for pharmacy services rendered, which services do not include marketing. Company B will not receive payment for the drugs themselves, which will be purchased by the University from drug manufacturers. The compensation will be based on a fixed amount per unit of anti-hemophilia factor dispensed; Company B has no control over the number of units dispensed. The parties have represented that Company B's compensation will represent fair market value in an arms-length transaction for the services rendered. Company B will be paid by the University, and not by patients or insurers, for services provided under the Agreement to patients participating in the University's outpatient pharmacy program.[(6)]

- Company B is not paying for referrals of Medicaid fee-for-service patients. Typically, contractual provisions that attempt to exclude Federal health care program business from an arrangement that might otherwise violate the anti-kickback statute are suspect, because often in practice the Federal health care program business is improperly affected by the tainted referral arrangement despite the purported "carve-out". Moreover, parallel arrangements that bifurcate services between Federal and private pay business may create a risk that parties will "swap" discounted private pay business for referrals of higher paying Federal business. The Proposed Arrangement contains several safeguards to minimize the risk of "swapping". First, under the Agreement Company B will not control the price charged for drugs for non-Medicaid patients and will not file claims for such drugs in its own right. Second, assuming

Company B's compensation under the Agreement will be fair market value for the term of the Agreement, and based on the parties' representation that the Agreement is and will be the only financial arrangement between the parties, there will be no remuneration from Company B to the University through the provision of free or below-market services. Hence, no inference arises that Company B is paying for referrals. Third, the exclusion of Medicaid fee-for-service patients contemplated by the Agreement is consistent with the section 340B bar on duplicate discounting and the Medicaid prohibition against reassignment.

- The Proposed Arrangement preserves patient freedom of choice. The Proposed Arrangement preserves freedom of choice for Medicaid fee-for-service patients by affording them the opportunity to use Company B as their pharmacy provider. In addition, all patients will be provided with (and will be required to acknowledge in writing) patient freedom of choice forms listing alternate pharmacy providers and disclosing the financial relationship between the University and Company B. Although such disclosures are not sufficient in and of themselves to mitigate the risk of fraud, they serve an important function by promoting informed patient decision-making.

III. CONCLUSION

For the above reasons and based on the facts as certified by the requesters, we conclude that, although the Proposed Arrangement might technically fall within the prohibition of the anti-kickback statute if the requisite intent were present, the OIG would not seek to impose sanctions under section 1128(b)(7) of the Act (as it relates to kickbacks) or section 1128A(a)(7) of the Act for payments made under the Agreement, provided the compensation is fair market value as certified by the requesters.[(7)]

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Company B and University A, the requesters 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.
- 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 Arrangement, nor is any opinion expressed regarding the parties' compliance with the 340B drug program.
- 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 that 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 Office of Inspector General ("OIG") will not proceed against the requesters 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, the compensation under the Agreement represents fair market value, and the Proposed 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, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the requesters 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, where the compensation under the Agreement represents fair market value, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

D. McCarty Thornton

Chief Counsel to the Inspector General

FOOTNOTES:

1. The price may not exceed the average manufacturers price for the drug reduced by a rebate percentage equal to the average total Medicaid drug rebate required under section 1927(c) of the Social Security Act divided by the average manufacturers price.

2. The requesters have represented that they are aware of no such state arrangement to date.

3. Although the parties have represented that the Agreement incorporates all of the suggestions contained in the Guidelines, we note that there appear to be some differences between the two. The differences are not material for purposes of analyzing the Agreement under the anti-kickback statute; we express no opinion regarding the Agreement's terms for any other purposes. For purposes of this opinion, we have assumed, based on the requesters' certifications, that the Proposed Arrangement will comply with the requirements of the 340B program.

4. Medicaid managed care patients are not excluded, because drugs purchased under capitated Medicaid managed care arrangements are not subject to the requirements of the Medicaid drug rebate program, and therefore there is no risk of duplicate discounting.

5. Because both the criminal and administrative sanctions related to the anti-kickback implications of the Arrangement are based on violations of the anti-kickback statute, the analysis for the purposes of this advisory opinion is the same under both.

6. We express no opinion regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, or other related conduct. We note, however, that Company B's compensation under the Agreement is not tied to the University's revenue, and therefore Company B does not appear to have any added incentive to upcode or otherwise bill in a manner that maximizes the University's reimbursement.

7. We are not authorized to opine on "fair market value." See section 1128D(b)(3) of the Act. Therefore, for purposes of this opinion, we have assumed fair market value compensation based on the requesters' certifications. If the compensation under the Agreement is not at fair market value, this opinion will be without force and effect.