

Posted July 6, 1998

[Name Redacted]

Re: Advisory Opinion No. 98-8

Dear [Name Redacted]:

We are writing in response to your request for an advisory opinion concerning whether Company A (“Company A”), a wholly-owned subsidiary of Company B (“Company B”) (collectively referred to as “Company AB”) would be subject to exclusion from Federal health care programs pursuant to 42 U.S.C. § 1320a-7(b)(6) for the submission of claims for durable medical equipment (“DME”) substantially in excess of its usual charges, if it charges Medicare 21-32% (based on five sample charges) more than it charges “cash and carry” retail customers for the identical DME products (“Proposed Arrangement”).

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an 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.

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 AB develops and operates, either by franchisees or through wholly-owned subsidiaries, a number of “superstores” that sell a wide selection of medical and health related products to customers for use in their homes. Company A, a wholly-owned subsidiary of Company B, operates a store occupying 5,000 square feet of retail space and offering a selection of over 3,000 different products. Product lines carried by Company AB include, but are not limited to, nutrition, back care, sports therapy, foot care, wound care, bathroom safety, personal care, oncology, and mobility and accessibility items.

Approximately 300 of the 3,000 products that Company AB sells are reimbursable under the Medicare program as DME, including urological, ostomy, orthotic, and wound care products. In order to participate in the Medicare program, a DME supplier must meet certain supplier standards. See 42 C.F.R. § 424.57. Medicare regulations allow a supplier to bill Medicare the lesser of (i) its actual charge to the patient for the equipment

or (ii) an amount calculated in accordance with a specific Medicare payment methodology, reduced by the applicable Part B deductible and coinsurance payments. See 42 U.S.C. § 1395m(a)(1)(B).

While Company AB does not currently participate in the Medicare program, Company A intends to apply to become a Medicare-approved supplier. Company AB proposes to charge Medicare an amount equal to the maximum reimbursement amount allowable under Medicare's payment regulations. According to Company AB, its proposed charges to Medicare will generally be higher than its charges to its "cash and carry" customers.

Company AB has determined that providing DME to Medicare beneficiaries will result in significant additional costs as compared to its "cash and carry" trade. Company AB has identified several areas where the Medicare supplier standards will create additional costs associated with serving Medicare beneficiaries.

- **Documentation Requirements** — The procedures necessary to obtain required physician prescriptions and certificates of medical necessity will increase costs due to the need to train staff and the time demands that will be placed upon that staff in assuring the completeness and accuracy of that documentation.
- **Claims Processing** — Rather than simply receiving cash in return for providing an item, Company AB will need to complete and submit claims for payment, requiring additional staff and upgrades for its computer system, in order to conduct intake for Medicare beneficiaries and process and track claims.
- **Delivery and Distribution** — Company AB will be required to deliver Medicare covered items upon request. Company AB will also need to rent or purchase warehouse space to operate a repair center and to store rental DME and returns.
- **Surety Bond** — The Health Care Financing Administration ("HCFA") has proposed a rule requiring DME suppliers to obtain a surety bond in favor of HCFA in an amount of not less than \$50,000. See 63 Fed. Reg. 2926, 2930 (Jan. 20, 1998).

Company AB asserts that additional costs will also be incurred in connection with Medicare requirements related to equipment leasing, product returns, and delays and denials in payment.

II. APPLICABLE LAWS AND ANALYSIS

Reimbursement to DME suppliers is determined according to the Medicare statute and regulations. With respect to a covered item of DME, the payment basis is the lesser of the actual charge for the item or the particular DME payment formula applicable to such item. See 42 U.S.C. § 1395m(a)(1). In general, most DME suppliers receive payment in the amount determined by the DME payment formula.

Under 42 U.S.C. § 1320a-7(b)(6), the Office of Inspector General has the authority to exclude individuals and entities from participation in the Federal health care programs (including Medicare) when it determines that an individual or entity has:

submitted or caused to be submitted bills or requests for payment (where such bills or requests are based on charges or cost) under subchapter VIII of this chapter . . . for items or services furnished substantially in excess of such individual's or entity's usual charges . . . for such items or services, unless the Secretary finds there is good cause for such bills or requests containing such charges or costs.

42 U.S.C. § 1320a-7(b)(6). Any permissive exclusion imposed under this section will be for not less than one year. See 42 U.S.C. § 1320a-7(c)(3)(F).

The OIG has promulgated regulations implementing this exclusion authority. The regulations state that charges substantially in excess of a supplier's usual charges are permissible when they are "due to unusual circumstances or medical complications requiring additional time, effort, expense or other good cause." 42 C.F.R. § 1007.701(c) (emphasis added).

Applying the statute and regulations, the initial inquiry is whether the proposed charges are substantially in excess of Company AB's usual charge. Currently, Company AB sells virtually all of its products, including the DME products that would be eligible for Medicare reimbursement, to customers on a "cash and carry" basis at posted prices. Accordingly, Company AB's usual charge for an item of DME is its current "cash and carry" price for that product. Because the amount Company AB proposes to charge Medicare is generally 21-32% higher than its "cash and carry" price for any given item, we believe that Company AB's charges to Medicare for some products would be substantially in excess of its usual charges and potentially subject Company AB to exclusion absent "good cause".

We agree that additional costs incurred by Company AB that are solely attributable to complying with Medicare requirements may constitute "good cause" for charging Medicare substantially in excess of Company AB's usual charge for identical items. However, the higher Medicare charge should bear a direct and reasonable relationship to the additional costs incurred by the supplier to comply with Medicare program requirements, after subtracting any costs solely attributable to the "cash and carry" business. These additional costs should be allocated to items provided to Medicare beneficiaries using a reasonable and generally accepted accounting methodology.

A useful benchmark for determining whether the higher Medicare charge would meet the "good cause" exception is to compare the profit margin on the Medicare sale to the margin on the "cash and carry" sale. So long as the profit margin for the Medicare sale is less than or equal to the "cash and carry" sale, we think the "good cause" exception would be satisfied.

On the limited information submitted, we cannot determine whether Company AB's proposed fee structure is sufficiently related to its anticipated additional costs attributable to Medicare participation to constitute "good cause" within the statutory and regulatory exception. In particular, Company AB has acknowledged that it does not yet know the entirety of the additional costs it will incur. Accordingly, we cannot determine whether Company AB's charge for any particular item would meet the "good cause" test, and therefore whether Company AB would be subject to exclusion under 42 U.S.C. 1320a-7(b)(6) for charging substantially in excess of its usual charges.

III. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Company A and Company B, which are 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 in the first paragraph of this advisory opinion. 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.

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- 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 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.

Sincerely,

D. McCarty Thornton
Chief Counsel to the Inspector General