



[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]

Issued: December 19, 2007

Posted: December 26, 2007

[Name and Address Redacted]

Re: OIG Advisory Opinion No. 07-17

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding your proposal to license to a new company the [invention redacted] you invented (the "Proposed Arrangement"). As an individual excluded from participation in Medicare, Medicaid, and other Federal health care programs, you have asked whether the Proposed Arrangement would constitute grounds for the imposition of sanctions against you under section 1128A(a)(6) of the Social Security Act (the "Act"), 42 U.S.C. § 1320a-7a(a)(6).

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

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 or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not violate your exclusion and would not constitute grounds for the imposition of administrative sanctions against you under section 1128A(a)(6) of the Act.

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

I. FACTUAL BACKGROUND

In June 2004, you pled guilty to [plea redacted], a misdemeanor under section 1128B(a)(2) of the Act. As a result of the guilty plea, you were sentenced to three years probation and fined \$2,000,000. In March 2005, the OIG excluded you from participation in Medicare, Medicaid, and all Federal health care programs for a mandatory five year period.

You have invented [invention redacted] (the “Invention”), and own the intellectual property associated with the Invention. You currently market the Invention outside of the United States, and now seek to introduce the Invention into the United States without violating the terms of your exclusion.

Under the Proposed Arrangement, your three adult children would create a new company (“Newco”) that would be completely independent of you. You would give Newco a royalty-free, non-exclusive license for the life of the patent for the Invention for sale or lease in the United States. Alternatively, Newco could decide to use the intellectual property associated with the Invention under a covenant with you, pursuant to which you would not sue Newco for infringement of your intellectual property rights.

The founders and initial investors in Newco would be your three adult children, who would invest their own money in Newco and would hire their own independent executive team to run Newco independent of you. Newco would be responsible for manufacturing the Invention and leasing or selling it to independent distributors who would then lease or sell the Invention to health care providers or suppliers. These providers or suppliers would submit claims to third party payers, including Federal health care programs.

You would have no ownership interest in Newco, and would have no relationship – financial or otherwise – with Newco. You would have no rights to current or future payments from Newco. Neither you nor any companies owned or managed by you would be investors, lenders, employees, managers, directors, consultants or have any control or role whatsoever in Newco.

You have certified that you would not furnish any item or service, either directly or indirectly, to a beneficiary of any Federal health care program. After you give the patent rights – with no present or future fees, royalties, balloon payments, or other payments – to Newco, you would have no involvement in Newco. You have certified that you understand that if at any time prior to the expiration of your exclusion you were to receive any financial benefit or the right to future financial benefits from Newco the Proposed Arrangement would violate the terms of your exclusion. You have also certified that you and your children have not made and will not make any agreement, either written or oral, during the term of your exclusion, which agreement would provide you with any financial benefit or right to future financial benefits during the term of your exclusion.

II. LEGAL ANALYSIS

A. Law

The basis for your exclusion is section 1128 of the Act. The following legal authorities are applicable in light of this exclusion.

An excluded individual that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil monetary penalty liability under section 1128(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(3) of the Act and other provisions. These actions also may serve as the basis for denying reinstatement to the Federal health care programs. 42 C.F.R. § 1001.1901(b)(3).

Pursuant to 42 C.F.R. §1001.1901, no payment may be made by Medicare, Medicaid, or any other Federal health care program for any item or service furnished by an excluded individual or entity during the period of exclusion. The Medicare payment prohibition is contained in section 1862(e) of the Act. The parallel Medicaid provision is found in section 1902(a)(39) of the Act, which requires states that receive payment for medical assistance to exclude from the Medicaid program any individual or entity excluded by the Secretary.

Pursuant to these authorities, the Federal health care programs do not pay for any items or services furnished directly or indirectly by an excluded person, regardless of who bills for such items or services. To furnish “indirectly” means to provide items or services manufactured, distributed, or otherwise supplied by individuals or entities who do not directly submit claims to Medicare, Medicaid, or other Federal health care programs, but that provide items or services to providers, practitioners, or suppliers who submit claims to these programs for such items and services. 42 C.F.R. § 1000.10.

B. Analysis

The Proposed Arrangement presents the question of whether you would be indirectly furnishing the Invention or causing claims for it to be submitted to Federal programs. For the following reasons, we conclude that the Proposed Arrangement would not violate your exclusion.

As a preliminary matter, it is clear that you would not directly submit claims for the Invention to Federal health care programs, and that you would not directly furnish any items or services that would be reimbursable by Federal programs.

Although you would not directly furnish or bill for the Invention, you would turn over the intellectual property associated with the Invention to Newco, which would manufacture and lease or sell the Invention to independent distributors, who would in turn lease or sell the Invention to health care providers or suppliers who could bill Federal health care programs

for it. In this scenario, we believe that the intervening and independent entities (i.e., Newco and its distributors), together with your certifications that you would have no relationship – financial or otherwise – with Newco, would sufficiently attenuate you from any claims submitted to Federal health care programs by downstream providers or suppliers that you would not be indirectly furnishing the Invention or causing claims for it to be submitted to Federal programs in violation of your exclusion.

Furthermore, you would not be a direct or indirect recipient of Federal health care program payments. You would have no ownership interest in Newco, and would have no financial relationships with Newco. You have further certified that you would have no rights to current or future payments from Newco.¹ Accordingly, there is little risk that Federal funds would make their way back to you through Newco.

Finally, we recognize that the Proposed Arrangement appears to contain a risk of Newco acting as a conduit for payments to you, in light of the filial relationship between the owners of Newco and you, their father. However, you have certified that no agreements, either written or oral, exist or will exist between you and your children that would provide you with any financial benefits from Newco.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion, we conclude that the Proposed Arrangement would not constitute grounds for the imposition of sanctions under section 1128A(a)(6) of the Act.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, 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 of this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule,

¹ Any exchange of value between you and Newco during the term of your exclusion for a future interest in Newco after the term of your exclusion would change our analysis and would likely result in an unfavorable opinion.

regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- 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.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

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

The OIG will not proceed against you 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 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, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against you 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. 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/

Lewis Morris
Chief Counsel to the Inspector General