Re: OIG Advisory Opinion No. 03-01

Dear [names redacted]:

We are writing in response to your request for an advisory opinion regarding the proposed employment (the “Employment”) of Dr. X (the “Physician”) by [name of company redacted] (“the Company”). The Physician is an individual excluded from participation in Medicare, Medicaid, and other Federal health care programs. You have asked whether the Employment would constitute grounds for the imposition of sanctions against the Company 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 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 Employment would not violate the Physician’s exclusion and would not constitute grounds for the imposition of administrative sanctions against the Company under section 1128A(a)(6) of the Act.
This opinion may not be relied on by any persons other than [names redacted] (the “Requestors”), and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

In November 2000, the Physician surrendered his license to practice as a physician in the [name of State redacted] after a complaint was filed against him by the [name of State redacted] Board of Medical Examiners. Based on that surrender, he was excluded by the Office of Inspector General (“OIG”) from participation in Medicare, Medicaid, and other Federal health care programs effective March 20, 2001.

The Company has made a good faith offer to employ the Physician, contingent on a favorable advisory opinion from the OIG. The Company is a for-profit corporation, incorporated in the [name of State redacted]. The Company provides data services to its clients, including data capture, analysis, and presentation. The Company also develops software applications for its clients. One division of the Company developed and supports a product (the “Product”) that computerizes x-ray images and stores them on computers for archival and reference purposes. The Company sells this Product to hospitals and radiology clinics, and it is reimbursable, in whole or in part, by Federal health care programs. The Company distributes no other products which are reimbursable by Federal health care programs, and is not involved, directly or indirectly, in the delivery of health care services or the claims filing for, or billing of, health care services. It does not provide utilization review, medical social work, or any other kinds of health care administrative services.

If the Company employs the Physician, the Physician would report to the Vice President for Business Development. His responsibilities would include: (i) business development, including development of sales materials and brochures and use of computer-driven presentations; (ii) software and database development, as well as testing and demonstration of proprietary software; (iii) writing reports, doing research, and generating report deliverables; and (iv) developing a smoking cessation program for industrial clients. The Physician would have no contact with federal program beneficiaries or providers of health care. The Physician would not be involved in the division of the Company which supports and markets the Product.

II. LAW

The basis for the Physician’s exclusion is § 1128(b)(4) of the Act, 42 U.S.C. § 1320(b)(4). The following legal authorities are applicable in light of this exclusion.

• 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.

• Section 1128A(a)(6) of the Act authorizes the imposition of civil monetary penalties (“CMPs”) against any person (including any entity) that employs, or enters into a contract with, excluded individuals or entities to provide items or services that are covered (or payable) by a Federal health care program, if the person knows or should know of the exclusion of the individual or entity. Under the CMP authority, a person may be subject to penalties of up to $10,000 for each item or service provided by the excluded individual or entity, an assessment of up to three times the amount claimed for such items or services, and a period of exclusion from all Federal health care programs.

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. Moreover, a person may not employ, or contract with, an excluded individual or entity to provide items or services payable in whole or in part, directly or indirectly, by any Federal health care program. These prohibitions extend to administrative and management services that are not directly related to patient care, but that are a component of providing items and services to Federal health care program beneficiaries. The prohibitions apply even if the excluded individual or entity providing the federally payable items or services is paid with non-federal funds, is paid by an unrelated third party, or provides items or services on an unpaid basis. In no event may federal program payment be made to cover an excluded individual’s salary, expenses, or fringe benefits. See generally, Special Advisory Bulletin: The Effect of Exclusion from Participation in Federal Health Care Programs, 64 F.R. 52791 (Sept. 30, 1999)
http://oig.hhs.gov/fraud/docs/alertsandbulletins/effect.htm
III. ANALYSIS

The Company seeking to employ the Physician indirectly furnishes items or services reimbursable under Federal health care programs. Although the Company does not directly submit claims to Medicare, Medicaid, or other Federal health care programs, it supplies the Product, which it developed and supports, to hospitals and other providers that submit claims to such programs for reimbursement, in whole or in part, related to the cost of the Product.

A provider or entity that receives Federal health care program funding may only employ an excluded individual in limited situations. Those situations would include instances where the provider or entity pays the individual’s salary, expenses, and benefits exclusively from private funds or from other non-federal funding sources, and where the services furnished by the excluded individual relate solely to non-federal programs or patients.

The issue raised by your request is whether the items and services that would be furnished by the Physician as an employee of the Company are sufficiently separable from the Product and the federal funds that pay for the Product that it would be reasonable (1) to view the services that the Physician would furnish as related solely to non-federal programs, and (2) to view the costs associated with the Physician’s employment (i.e. salary, expenses, and benefits) as paid by non-federal funding sources.

Based on the Requestors’ representations about the Physician’s prospective employment responsibilities, the Physician would furnish no items or services that are reimbursable, directly or indirectly, by any Federal health care programs and would have no association with the division of the Company that provides such items and services. As such, the purpose and costs of the Employment would be so attenuated from any federal program funds received by the Company that we conclude that the Employment (as described and certified in your request for an advisory opinion and supplemental submissions) would not violate the Physician’s exclusion and would not constitute grounds for the imposition of administrative sanctions against the Company under section 1128A(a)(6) of the Act.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

C This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

C 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 section 1128A(a)(6) of the Act. No opinion is expressed or implied herein 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 Employment.

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.

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 the Requestors with respect to any action that is part of the Employment 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 Employment 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 the Requestors 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 the Employment in practice comport with the information provided 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,

Lewis Morris
Chief Counsel to the Inspector General