DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of Inspector General
Washington, D.C. 20201

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

Issued: May 26, 2004

Posted: June 2, 2004

[name and address redacted]

Re: OIG Advisory Opinion No. 04-4

Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposed program to provide free vision screening tests for infants (the "Proposed Program"). Specifically, you have inquired whether the Proposed Program constitutes grounds for the imposition of sanctions under the civil monetary penalty ("CMP") provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of the Act or the CMP provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act.

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: (i) because the Proposed Program would satisfy all of the requirements of the preventive care exception, the Proposed Program would not constitute prohibited remuneration within the meaning of section 1128A(a)(5) of the Act; and (ii) the Proposed Program could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal

health care program business were present, but that the Office of Inspector General ("OIG") would not impose administrative sanctions on [Entity X], [Entity Y], or [optometrist's name redacted], under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Program.

This opinion may not be relied on by any persons other than [Entity X], [Entity Y], and [optometrist's name redacted], the requestors of this opinion (the "Requestors"), and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

1. FACTUAL BACKGROUND

The Requestors are (i) the [Entity X] (the "Association"), a federation of state, student, and armed forces optometric associations serving members consisting of optometrists, students of optometry, paraoptometric assistants, and technicians,[1] (ii) the [Entity Y], a nonprofit corporation exempt from Federal taxation (the "Charitable Organization"), formed by the Association to provide educational, scientific, and charitable services, and (iii) [optometrist's name redacted], a licensed optometrist serving as a member of the Association's Board of Trustees and as the director of the Proposed Program (the "Program Director"). The Program Director will serve on a volunteer basis, without compensation, and will be a participating Association optometrist under the Proposed Program.

In 2002, the Association and the U.S. Department of Health and Human Services (the "Department") entered into a memorandum of understanding ("MOU") regarding activities related to the vision objectives of Healthy People 2010, a national health promotion and disease prevention initiative sponsored by the Department. Healthy People 2010 has ten specific vision objectives, including (i) increasing the proportion of preschool children aged five years and under that receive vision screening and (ii) reducing blindness and visual impairment in children aged seventeen and under. The Association created the Proposed Program, named [program name redacted], in furtherance of Healthy People 2010's vision objectives.

The Proposed Program addresses the occurrence of undetected amblyopia (also known as "lazy eye") in children by providing free vision screening to infants between the ages of six and twelve months, some of whom may be covered by Medicaid. Under the Proposed Program, the screenings will be provided by optometrists who are members of the Association and otherwise qualified to provide such screenings under applicable state licensure law. Although the Association will invite each of its member optometrists to

[1]Optometrists who are members of the Association must pay annual dues.

participate in the Proposed Program, participation is voluntary. To participate, an Association optometrist must agree: (i) to provide vision screening to any infant between the ages of six and twelve months free of charge (i.e., without billing the patient, the patient's family, or any insurer or third-party payer, including any Federal health care program); and (ii) not to condition the free screening services on any other services, including, without limitation, services covered by any Federal health care program.

The Association will maintain a registry of participating Association optometrists, and it will provide two methods to access the registry. Under the first method, the infant's parent or guardian would use the Association's internet doctor locator service to obtain a list of Association optometrists within a designated zip code, city, or state. The list would identify those Association optometrists who are participating in the Proposed Program. Under the second method, the infant's parent or guardian would call a toll-free telephone number and give the Association representative his or her name, address, and telephone number. The Association would then mail a list of participating Association optometrists to the caller. The Requestors have certified that the Association will not recommend a particular optometrist or otherwise influence the selection process.

The Requestors anticipate that the vast majority of infants screened under the Proposed Program will screen negative for amblyopia and will not require further testing or follow-up care.[2] For infants without risk factors, the Association recommends that the next examination occur at age three. For those infants who screen positive for amblyopia or amblyogenic risk factors, participating Association optometrists may recommend additional examinations, treatment, or therapies, none of which would be covered by the Proposed Program, but some of which may be Medicaid-reimbursable. If the optometrist recommends additional examinations, treatments, or therapies, the optometrist will inform the infant's parent or guardian verbally and in writing of his or her freedom to choose any practitioner. Some of the additional examinations, treatments, and therapies may be Medicaid-reimbursable.

The Association and the Charitable Organization will bear the cost of establishing and administering the Proposed Program. The Association will train participating Association optometrists on the examination of infants and provide forms for use in

---

[2]According to the Requestors, in a scientific study conducted in Israel, 3.6% of the 988 infants screened were suspected of having amblyopia or amblyogenic risk factors and were required to have more thorough examinations, and 2.2% of the 988 infants were confirmed to have amblyopia or amblyogenic risk factors. See Eibschitz-Tsimhoni, Friedman, Naor, Eibschitz, and Friedman, Early Screening for Amblyogenic Risk Factors Lowers the Prevalence an Severity of Amblyopia, 4 Journal of the American Association for Pediatric Ophthalmology and Strabismus 194 (August 2000).

connection with the screening. The Association will ask participating optometrists to report the results of the screenings to the Association.[3] The Association will promote the Proposed Program through the Association and its affiliated state optometric associations, county health departments and related agencies and organizations, and the Program Director and other participating Association optometrists, who may contact their respective patients and inform them of the Proposed Program.

II. LEGAL ANALYSIS

Section 1128A(a)(5) of the Act prohibits a person from offering or transferring remuneration to a beneficiary that such person knows or should know is likely to influence the beneficiary to order or receive items or services from a particular provider, practitioner, or supplier for which payment may be made under the Medicare or Medicaid programs. See also 42 C.F.R. § 1003.102(b)(13). Where a party commits an act described in section 1128A(a)(5) of the Act, the OIG may initiate administrative proceedings to impose CMPs on the party and to exclude the party from the Federal health care programs.

The statute contains an exception for incentives given to individuals to promote the delivery of preventive care. See section 1128A(i)(6)(D) of the Act. The regulations exclude from the definition of "remuneration" incentives "given to individuals to promote the delivery of preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by Medicare or an applicable State health care program." See 42 C.F.R. § 1003.101. The rule defines "preventive care" to mean any service that "(1) [i]s a prenatal service or post-natal well-baby visit or is a specific clinical service described in the current U.S. Preventive Services Task Force's Guide to Clinical Preventive Services [the "Guide"], and (2) [i]s reimbursable in whole or in part by Medicare or an applicable State health care program." Id. The Guide provides that "[v]ision screening to detect amblyopia . . . is recommended once for all children prior to entering school, preferably between ages 3 and 4."

Under the Proposed Program, participating Association optometrists would provide free vision screening services to infants, some of whom would be Medicaid beneficiaries.

---

[3]The Association has certified that it will not request from participating Association optometrists health information that is protected under 45 C.F.R. Parts 160 and 164 (the "Privacy Rule"), the regulations implementing Title II, Subtitle F, section 264 of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191. We express no opinion on the application of the Privacy Rule or any other privacy law or regulation to the Proposed Program.

Thus, the Proposed Program implicates section 1128A(a)(5) of the Act. However, if the Proposed Program satisfies all of the criteria of the preventive care exception, it would not involve prohibited remuneration within the meaning of section 1128A(a)(5) of the Act.

In the instant case, services provided under the Proposed Program satisfy the regulatory definition of preventive care; the screening services are both described in the current Guide and reimbursable by at least some State health care programs.[4] Therefore, to determine whether the Proposed Program qualifies for the preventive care exception, the key inquiry is whether the Proposed Program impermissibly ties preventive care services to other Medicare- or Medicaid-reimbursable services. Based on the facts presented, the Proposed Program contains the following safeguards that, in combination, should ensure that there is no impermissible tying of such services.

First, participating optometrists agree not to condition the free vision screening services in any manner on the receipt of any other services. To further safeguard patient choice, if follow-up care is required, participating Association optometrists will inform each infant's parent or guardian of his or her freedom to choose other providers verbally and in writing.

Second, very few infants will require follow-up care for detected amblyopia; for the vast majority who will screen negative, the next recommended screening would occur more than a year after the free screening, so that any potential nexus would be tenuous at best.

Third, the Proposed Program is structured so that the parent or guardian will initially select a participating optometrist from a list of all participating Association optometrists based upon factors that the parent or guardian deems important, such as, for example, proximity or office hours. To the extent the same optometrist is selected for follow-up care, the decision is likely to be attributable to the earlier innocuous considerations rather than the free screening. The Association will not recommend particular optometrists for screenings or follow-up care.

Fourth, participating optometrists must agree to provide a free screening to any infant between the ages of six and twelve months, the vast majority of whom will not require any follow-up care. Therefore, any financial gain resulting from subsequent paid visits would be offset, at least in part, by costs associated with furnishing the free services.

---

[4]For purposes of determining whether a service qualifies as preventive care under 42 C.F.R. § 1003.101, the Guide's effectiveness measures (including, for example, suggested ages for preventive screenings) are not taken into account. See 65 Fed. Reg. 24400, 24408 (April 26, 2000).

Fifth, the Association and the Charitable Organization will bear the training and administrative costs of the Proposed Program, thereby, reducing any potential incentive that the optometrist might otherwise have to recommend follow-up care to recoup such costs.

Finally, in addition to these safeguards, the free vision screening services will confer a public benefit by promoting early vision screening for children, furthering both the charitable mission of the Charitable Organization and the important goals of the Department's Healthy People 2010 initiative.

For the combination of reasons listed above, we conclude that the free vision screening services provided to infants under the Proposed Program satisfy all of the requirements of the preventive care exception and, therefore, would not constitute prohibited remuneration within the meaning of section 1128A(a)(5) of the Act. For the same reasons, we conclude that we would not subject the Requestors to administrative sanctions under the anti-kickback statute in connection with the remuneration provided to infants under the Proposed Program.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) because the Proposed Program would satisfy all of the requirements of the preventive care exception, the Proposed Program would not constitute prohibited remuneration within the meaning of section 1128A(a)(5) of the Act; and (ii) the Proposed Program could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on [Entity X], [Entity Y], or [optometrist's name redacted], under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Program.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Entity X], [Entity Y], and [optometrist's name redacted], the requestors 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, regulation, ordinance, or other law that may be applicable to the Proposed Program, 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 the Requestors with respect to any action that is part of the Proposed Program 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 Program 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 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