

*[We have redacted certain identifying information regarding the requesters and certain potentially privileged, confidential or proprietary information associated with the individual or entity, unless otherwise specified by the requesters.]*

Date Issued: June 30, 1999

Date Posted: July 9, 1999

[name and address redacted]

[name and tile redacted]

National Eye Care Project

P.O. Box 429098

San Francisco, CA 94142

**Re: OIG Advisory Opinion No. 99-7**

Dear [name redacted] and [name redacted]:

We are writing in response to your request for an advisory opinion concerning the National Eye Care Project ("NECP") and Dr. A's participation in the NECP. A key component of the NECP involves an insurance only billing policy (i.e., an across-the-board waiver of any out-of-pocket beneficiary copayments) for medical services covered by the NECP. Specifically, you have requested confirmation that this policy does not constitute grounds for the imposition of a sanction under section 1128A(a)(5) of the Social Security Act (the "Act"), which prohibits the offering of inducements to beneficiaries in order to influence their selection of a provider for Medicare or Medicaid covered services.

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 information provided, the insurance only billing practice (to the extent it results in waivers of coinsurance obligations for eligible Medicare or Medicaid patients referred by the NECP) constitutes prohibited remuneration within the meaning of section 1128A(a)(5). Notwithstanding, for the reasons set forth below and subject to certain conditions described below, in the particular circumstances presented, the OIG will not subject the NECP or Dr. A (as a participating NECP ophthalmologist) to sanctions under section 1128A(a)(5).<sup>(1)</sup>

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

**FACTUAL BACKGROUND**

The National Eye Care Project is a public outreach program that provides medical eye care for eligible senior citizens. The program began in 1983 and is cosponsored by the Foundation of the American Academy of Ophthalmology ("Foundation") and the Knights Templar Eye Foundation, Inc. Dr. A is the [title redacted] and is one of the participating ophthalmologists.

The NECP encourages elderly citizens to protect their eyesight by having a comprehensive eye exam and any needed treatment. The Foundation has set up a referral network of ophthalmologists who agree to provide a comprehensive medical eye examination and up to twelve months of follow-up care for any condition diagnosed at the initial visit without any out-of-pocket cost to the NECP patients. The NECP does not cover eyeglasses, prescription drugs, hospital services, or services of other medical professionals.<sup>(2)</sup>

Participating ophthalmologists agree to accept insurance reimbursement as payment in full for care rendered to the NECP patients; no copayments or deductibles (collectively referred to as "coinsurance") are collected from any patient for the treatment of any condition diagnosed at the initial visit. If the treatment continues for more than one year after the initial diagnosis, a participating ophthalmologist may waive the coinsurance only if he or she determines that the patient is in financial need according to an individualized need determination performed by the ophthalmologist. If a patient has no insurance coverage, the participating ophthalmologist will render eye care without charge.

The NECP is promoted through public service announcements by the Foundation. Individual ophthalmologists do not refer patients to, or advertise their participation in, the NECP. The advertisements encourage the elderly to call an 800 number maintained by the Foundation, either for free eye care information or for referral to a participating ophthalmologist. A caller to the Foundation's 800 number who wishes to see an ophthalmologist is screened for eligibility. Individuals are eligible if they are U.S. citizens or legal residents, age 65 and older, who have not seen an ophthalmologist in the past three years.<sup>(3)</sup> In most cases, the NECP will only refer a caller once.

Once a person is determined to be eligible, he or she is assigned to a participating ophthalmologist by a computer program that uses zip codes and geographic proximity to match the person with a nearby participating ophthalmologist. Computer assignments are made on a rotating basis; a physician only receives a second patient after all other participating ophthalmologists in that area have been assigned a first patient. In addition, participating ophthalmologists cannot examine or treat more than fifteen new NECP patients in any one calendar year. The only exception to this limit is for participating ophthalmologists practicing in health professional shortage areas or medically underserved areas. Consequently, the number of NECP patients any participating ophthalmologist sees is unlikely to constitute a significant proportion of his or her practice.

The NECP has received national recognition during its sixteen year history, including the President's Citation for Private Sector Initiative in 1986 and 1988, the American Medical Association's President's Citation for Service to the Public, the American Association of Retired Persons Award for Public Service, and more than thirty other citations and commendations from government agencies.

Prior to the initial implementation of the NECP, the Foundation consulted with the OIG to assure that the program would not violate the anti-kickback statute. In a letter dated October 30, 1984, then Inspector General Richard P. Kusserow approved the NECP as long as: (i) all ophthalmologists are free to participate; (ii) the ophthalmologists who participate are aware of Medicare reimbursement policy for ophthalmological services; (iii) referrals by the project to ophthalmologists are made on a rotating basis; and (iv) the number of beneficiaries for whom coinsurance is waived does not constitute a significant proportion of any one ophthalmologist's practice. The NECP has certified that it is in compliance with these requirements.

Prior to enactment of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the NECP requested that participating ophthalmologists waive the coinsurance for eligible patients referred to them by the NECP without performing any financial need determination. However, as of January 1, 1997, when HIPAA took effect, the NECP modified its program to comply with section 231(h) of HIPAA, now section 1128A(a)(5) of the Act (described below), and narrowed the focus of its advertising and outreach efforts to target only seniors who would meet financial need criteria. Information sheets were modified to read: "For seniors without the means to pay, the fees for the examination and treatment are waived." (emphasis added). When potential patients telephone the NECP, operators now perform a financial need analysis before the patients are referred to a participating physician. As a result of this and other factors (such as a decrease in advertising by the NECP), the number of callers dropped from 5,698 in 1996 to 1,913 in 1997.

The NECP has requested an opinion as to whether its former practice of insurance only billing for all patients irrespective of financial need would run afoul of section 1128A(a)(5) of the Act.

## **II. THE NECP'S WAIVER OF COINSURANCE IMPLICATES THE CIVIL MONETARY PENALTY PROHIBITING INDUCEMENTS TO BENEFICIARIES.**

### **Applicable Law**

Section 1128A(a)(5) of the Act prohibits a person from offering or transferring remuneration to any individual eligible for benefits under Medicare or Medicaid that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under Medicare or Medicaid. For purposes of this section, "remuneration" is defined as including the waiver of coinsurance amounts, except in certain narrowly defined circumstances, such as copayment waivers that are not advertised, not routine, and made after a good faith financial determination. The definition of remuneration also includes an exception for certain incentives given to individuals to promote the delivery of preventive care. See Section 1128A(i)(6)(D) of the Act.<sup>(4)</sup>

### **Analysis**

The NECP clearly falls within the activities proscribed by section 1128A(a)(5) of the Act. Congress specifically included waivers of coinsurance in its statutory definition of "remuneration." However laudatory the goal, the NECP uses the promise of free care to motivate otherwise reluctant patients to undergo eye examination and treatment (if needed). In short, the patient visits the particular ophthalmologist identified by the NECP because the patient is told that the ophthalmologist will waive any out-of-pocket costs associated with the treatment.

The statutory proscription in section 1128A(a)(5) of the Act reflects serious programmatic concerns with waivers of coinsurance. We published a Special Fraud Alert ("Fraud Alert") in May 1991, which stated that providers who routinely waive Medicare Part B coinsurance may be held liable under the anti-kickback statute. See Special Fraud Alert, reprinted in 59 Fed. Reg. 242 (1994). Although the Fraud Alert pre-dates the passage of section 1128A(a)(5) and therefore addresses only the potential problems under the anti-kickback and false claims statutes, the programmatic concerns are identical. When providers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be inducing the patient to use items or services that are unnecessary, simply because they are free. Thus, except in those special cases specifically excepted from section 1128A(a)(5), Medicare Part B waivers of coinsurance are highly problematic.

However, for the reasons set forth below, we conclude that we will not impose sanctions on the NECP under section 1128A(a)(5) of the Act in the particular circumstances presented here. We stress that, standing alone, none of the factors below would assure us that the NECP program is not prone to fraud and abuse, nor would we necessarily reach the same conclusion if we were reviewing the NECP for the first time. However, because of the NECP's reliance on prior written approval from the Inspector General, coupled with the unique nature of the program and the safeguards the NECP has put in place, we will not impose sanctions.

First, our determination is based on our recognition that the NECP program was created nearly fifteen years ago in reliance on explicit approval from this Office. When the NECP was first developed, its counsel consulted the OIG and, on October 30, 1984, then Inspector General Kusserow issued a letter to the NECP that approved the project, as long as (i) all ophthalmologists are free to participate; (ii) the ophthalmologists who participate are aware of Medicare reimbursement policy for ophthalmological services; (iii) referrals by the project to ophthalmologists are made on a rotating basis; and (iv) the number of beneficiaries for whom coinsurance is waived does not constitute a significant proportion of any one ophthalmologist's practice. The NECP has operated its program in reliance on this approval.

Second, we are not aware of any documented overutilization by participating ophthalmologists or any other documented abuses associated with the NECP during its fifteen years of operation. While no demonstration of harm is required by section 1128A(a)(5) or many of the other health care fraud and abuse authorities, in this particular instance -- where the NECP sought and received official written approval in advance of operation and

has complied with the terms of that approval -- it is reasonable to take the absence of any evidence of abuse into consideration.

Third, while the NECP is over-inclusive in that the waiver of coinsurance is not limited to the financially needy, the NECP has nevertheless provided a significant benefit to financially needy individuals who may not otherwise have sought or received care. The NECP has been recognized by, and received awards from, the public and private sectors for its benefits to public welfare including recognition by several United States Presidents and the American Medical Association. Congressional recognition of the value of the NECP and of the inadvertent impact of section 1128A(a)(5) on the NECP was a major impetus in the recent amendment specifically confirming the Secretary's discretion under section 1128D(b)(2)(E) of the Act to exempt certain practices that would otherwise be prohibited under section 1128A(a)(5). See Pub. L. No. 105-277 (1998); 144 Cong. Rec. H10243, 10253 & 10258 (1998) ("HHS is authorized to issue an advisory opinion permitting waiver of [the coinsurance and deductibles] requirements with regard to [services provided by the NECP].") (statement of Rep. Stearns).

Fourth, at least some parts of the comprehensive eye examination given to the NECP patients on their initial visit constitute preventive care services and would be exempt from the definition of remuneration in any event. See Section 1128A(i)(6)(D) of the Act.

Finally, the benefit to any one ophthalmologist is limited. The rotating basis upon which the NECP pairs eligible patients with ophthalmologists greatly reduces the risk that an ophthalmologist participating in the NECP could benefit in any significant way from the NECP referrals, thus minimizing any risk of fraud and abuse. Participating ophthalmologists do not advertise that they participate in the NECP and cannot refer patients to themselves through the NECP. A computer assigns the eligible patients on a rotating basis. Each participating ophthalmologist in a location (defined by zip code and geographic proximity) receives one patient before any other participating ophthalmologist in that area receives a second patient.

Moreover, ophthalmologists cannot examine or treat more than fifteen new NECP patients in any one calendar year.<sup>(5)</sup> The only exceptions to this policy are for ophthalmologists practicing in health professional shortage areas or medically underserved areas. Consequently, the number of NECP patients is not likely to constitute a significant percentage of any participating ophthalmologist's practice.

### **III. CONCLUSION**

For the above reasons and based on the facts as certified in the request letter and supplemental submissions, we conclude that the insurance only billing practice (to the extent it results in waivers of coinsurance obligations for eligible Medicare or Medicaid patients referred by the NECP) constitutes prohibited remuneration within the meaning of section 1128A(a)(5). Notwithstanding, for the reasons and subject to the conditions set forth above, in the particular circumstances presented, the OIG will not subject the NECP or Dr. A (as a participating NECP ophthalmologist) to sanctions under section 1128A(a)(5) of the Act.

### **IV. LIMITATIONS**

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Dr. A, and the National Eye Care Project, the requesters 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 requester 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 NECP or Dr. A.

- 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 requesters with respect to any action that is part of the NECP 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 NECP and Dr. A comply with the certifications 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 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. 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.
2. If hospital care is needed, the participating ophthalmologist requests that the hospital provide the services without charge. We express no opinion with respect to this practice.
3. Individuals enrolled in prepaid health care plans or who receive care through the armed forces or Veterans Administration hospitals are not eligible.
4. The other permissible exceptions to the civil money penalty are: (i) failure to collect after reasonable collection efforts; (ii) differentials in coinsurance as a part of a benefit plan design; and (iii) payment practices safe harbored under section 1128B(b)(3) of the Act or in regulations under section 42 C.F.R. § 1001.952.

5. We do not intend the fifteen patient cap to create a de minimis exception to the prohibition on waivers of coinsurance under section 1128A(a)(5) of the Act. We reiterate that this factor must be read in conjunction with all of the reasons set forth in this opinion.