



[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: August 3, 2009

Posted: August 10, 2009

[Name and address redacted]

Re: OIG Advisory Opinion No. 09-11

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding the provision of free blood pressure screenings to walk-in visitors at a hospital (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under the civil monetary penalty 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 civil monetary penalty 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, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, 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) the Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Arrangement 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, the Office of Inspector General ("OIG") will not impose

administrative sanctions on [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 Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

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

[Name redacted] (the “Hospital”) is a small county-owned critical access hospital in northwest [state name redacted].¹ Under the Arrangement, the Hospital provides a free blood pressure check to any visitor who enters requesting this service during daylight hours. Should a member of the public call in to inquire about the service, the Hospital indicates that it provides a free blood pressure check to any visitor who enters requesting this service during daylight hours.² The Hospital certifies that it does not advertise the free blood pressure check service to the public. The free blood pressure check is provided in accordance with the Hospital’s own specific guidelines and procedural checklists. It is conducted by a member of the Hospital nursing staff who is on-duty and available at the time the visitor presents.

The Hospital certifies that the free blood pressure check is not conditioned on the visitor’s use of any other goods or services from the Hospital or any other particular health care practitioner or provider. The Hospital certifies that the visitor receiving the blood pressure check is not directed by Hospital staff or administration to the Hospital or any other particular health care practitioner or provider. The Hospital does not offer the visitor any special discounts on follow-up services. When a visitor’s blood pressure reads outside of normal limits, the visitor is advised to see his or her own health care professional.³ While some who receive the free blood pressure check are Medicare or

¹The hospital administration also operates two Medicare-certified rural health clinics. There are no competitive hospitals or health clinics in the Hospital’s remote service area.

²Some callers to the hospital, not initially interested in blood pressure screening, are advised based on the nature of their complaints to come into the hospital for examination. Such visits may involve a blood pressure check but are not part of this request for opinion.

³In the case of an abnormal blood pressure reading, the charge nurse is notified per Hospital procedure. Where clinical circumstances demand it, the visitor may be directed

Medicaid beneficiaries, the Hospital does not bill the blood pressure check service to any Federal health care program or any other third-party payors.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

Section 1128A(a)(5) of the Act (the “CMP”) provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or state health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines “remuneration” for purposes of section 1128A(a)(5) as including “transfers of items or services for free or for other than

to an emergency room examination and possibly emergency treatment. Such a procedure may be required by the Emergency Medical Treatment and Active Labor Act (“EMTALA”). Whether the Hospital’s blood pressure check procedure complies with EMTALA requirements is beyond the scope of this advisory opinion.

fair market value.” The OIG has previously taken the position that “incentives that are only nominal in value are not prohibited by the statute,” and has interpreted “nominal value to be no more than \$10 per item, or \$50 in the aggregate on an annual basis.” 65 Fed. Reg. 24400, 24410 – 24411 (April 26, 2000) (preamble to the final rule on the CMP).

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. Such incentives may include the provision of preventive care” See 42 C.F.R. Sec. 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 a recommendation for “screening for high blood pressure in adults over the age of 18.”

B. Analysis

Under the Arrangement, the Hospital provides free blood pressure checks to visitors, some of whom are Medicare and Medicaid beneficiaries. The Hospital did not indicate the fair market value of these screenings; however, because there is no limit on the number of times that an individual may be screened, for at least some beneficiaries, the aggregate annual value of the multiple screenings could exceed \$50, even if the value of single screening does not exceed \$10. Thus, the Arrangement implicates section 1128A(a)(5) of the Act.

Blood pressure checks meet the definition of a preventive care service in some circumstances. For any type of free care offered by a provider, however, regardless of whether it is preventive care as defined in the regulation, it is necessary to determine whether the free care promotes the provision of other, nonpreventive care reimbursed by Medicare or Medicaid. We conclude that in the Arrangement, the free blood pressure checks are unlikely to have this effect.

In our preamble to the 2000 final rule on the CMP at 65 Fed. Reg. 24400 (April 26, 2000), we discussed a hypothetical situation very similar to the Arrangement. A commenter asked if a hospital could offer free blood screenings that were not covered by Medicare. We indicated as follows:

[P]rovision of a free non-covered screening test would not violate [the CMP] so long as the test is not tied to provision of services by the hospital. Thus, for example, the screening test would be permissible where the hospital provides an individual who tests positive for diabetes with general information or literature and a recommendation that the individual contact his or her personal physician. If, on the other hand, as part of the screening program, the hospital makes appointments for individuals with one of its physicians, offers individuals discounts for additional covered services, or otherwise promotes its particular diabetes programs, an inference may be drawn that the free screening test was an inducement to choose the hospital as a provider of other services.

65 Fed. Reg. 24400, 24410 (April 26, 2000). The Arrangement is closely analogous to the permissible screening test program discussed in the preamble. The free blood pressure check offered by the Hospital under the Arrangement is not conditioned on use of any other goods or services from the Hospital or any other particular practitioner or provider. Nor is the visitor receiving the blood pressure check directed to any particular health care practitioner or provider. The Hospital does not offer the visitor any special discounts on follow-up services. Staff responds to an abnormal blood pressure reading obtained during a free check by advising the visitor to see his or her own health care professional.⁴ In sum, the Arrangement is appropriately crafted so as to avoid improper ties to the provision of other services.

For all of the reasons set forth above, we conclude that the Arrangement does not violate the prohibition on beneficiary inducements. For these same reasons, we conclude that we would not impose administrative sanctions arising in connection with either the anti-kickback statute or the CMP on the Hospital in connection with the Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Arrangement 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, the OIG will not impose administrative sanctions on

⁴As noted, clinical circumstances and EMTALA may require that staff direct the visitor to an emergency room examination and emergency treatment. In light of all of the Arrangement's facts and circumstances, we do not consider that the possibility of a referral in these emergency circumstances creates a risk of violation of the CMP or the anti-kickback statute.

[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 Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

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, regulation, ordinance, or other law that may be applicable to the 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 [name redacted] with respect to any action that is part of the 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 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 [name redacted] 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General