

[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 27, 2001

Posted: September 4, 2001

[name and address redacted]

Re: OIG Advisory Opinion No. 01-14

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a hospital's policy of waiving out-of-pocket copayments and deductibles ("coinsurance") for screening services and certain follow-up services that the hospital offers to promote early detection of breast and gynecological cancers (the "Waiver Policy"). Specifically, you have inquired whether the Waiver Policy 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 the Waiver Policy may potentially generate prohibited remuneration under the CMP for inducements to beneficiaries and 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”) will not impose administrative sanctions on [name redacted] in connection with the Waiver Policy for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Act nor for violations of the anti-kickback statute 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).

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], a [State X] not-for-profit corporation (the “Hospital”), operates a cancer hospital at its main campus and the [name redacted] (the “Center”) at a satellite location in [Community Y], a neighborhood within [City Z]. The Center, an operating division of the Hospital, offers an early detection program for breast and gynecological cancers “at no out-of-pocket expense” to its patients. It is financed by a series of Federal and state grants, private philanthropic support, and, to the extent that grant funds do not cover its annual total operating expenses, by annual grants from the Hospital.¹ The Center’s office space is owned by [State X] and provided to the Center rent free.

The Center’s early detection program includes breast and gynecological cancer screening services provided at the Center (the “Screening Services”), certain follow-up services provided at other Hospital facilities, including the cancer hospital at the main campus (the “Follow-Up Services”), and related educational, counseling, and referral services. The Screening Services include: a clinical breast examination; a screening mammogram using one of the Center’s three mammography machines, together with interpretation of the mammography film by a Hospital radiologist; a screening pelvic examination; and/or a screening pap smear. If a patient receives an abnormal result from the Screening

¹Some of the Center’s grant funds derive indirectly from the National Breast and Cervical Cancer Early Detection Program, a program administered by the Centers for Disease Control and Prevention to provide breast and cervical cancer screening services to underserved women, including older women, women with low incomes, and women of racial and ethnic minority groups.

Services, a Center employee calls the patient to schedule a Follow-Up Service, which is typically performed at a Hospital facility other than the Center. Follow-Up Services include: (i) for an abnormal mammogram, an ultrasound or diagnostic mammogram and/or a needle biopsy or aspiration with or without ultrasound guidance, together with interpretation of the results by a Hospital physician; and/or (ii) for an abnormal pap smear, an office visit with a gynecologist and any related, confirming procedures, including, for example, a repeat pap smear or colposcopy.

If concerns persist after the Follow-Up Services, the patient is seen by one of three Center surgeons and scheduled for additional services (most often surgery), usually at one of three hospitals with which the attending Center physician has admitting privileges.² These hospitals are not affiliated with, or owned in any manner by, the Hospital, and the Hospital receives no financial recompense for such referrals or arrangements. Patients may elect to receive the required additional services at the Hospital. However, this happens infrequently and, when it does, the Waiver Policy ceases to apply (i.e., all of the Hospital's standard patient billing and payment policies apply, including billing patients for coinsurance, except in cases of individualized determinations of financial need).

The Center's outreach program targets [Community Y], which consists largely of individuals of African or Hispanic origin. To encourage use of its services, the Center instituted the Waiver Policy, which it publicizes in connection with its community outreach program. Under the Waiver Policy, the Center accepts reimbursement from its patients' third party payors, if any, as payment in full for the Screening Services and Follow-Up Services. Thus, the Center waives any out-of-pocket coinsurance obligation for Screening Services and Follow-Up Services provided to its insured patients, and it waives the entire charge for its uninsured patients.

Although, in recent periods, a majority of the Center's patients (i.e., approximately 67%) are uninsured, some of its patients are Medicaid beneficiaries (i.e., approximately 12%) and some are Medicare beneficiaries (i.e., approximately 5%). The Screening Services and Follow-Up Services are potentially reimbursable by Medicare and Medicaid. Pursuant to Federal law, the usual Medicare Part B deductible is waived for screening mammographies and screening pelvic examinations, but the Medicare Part B copayment applies. See section 1833(b) of the Act. The Screening Services and Follow-Up Services are also reimbursable under the [State X] Medicaid Program with nominal copayments.

²The three Center physicians are retained, paid, and credentialed by the Hospital solely to provide services at the Center, but they are not full-time staff physicians at the Hospital. Each Center physician has staff privileges at one or more of three hospitals, which are closer geographically to most Center patients' residences than the Hospital.

II. LEGAL ANALYSIS

A. Law

Waivers of Medicare and Medicaid program coinsurance amounts implicate section 1128A(a)(5) of the Act, which 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 such party. For purposes of section 1128A(a)(5) of the Act, “remuneration” expressly includes the waiver of coinsurance. See section 1128A(i)(6) of the Act.

The statute contains an exception for incentives given to individuals to promote the delivery of preventive care. See section 1128A(i)(6) of the Act. The final rule addressing the statutory exception excludes 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, and (2) is reimbursable in whole or in part by Medicare or an applicable State health care program.” Id. The Guide currently describes screening for breast cancer, which includes a mammography alone or mammography and annual clinical breast examination, and screening for cervical cancer, which includes a pap smear. In addition, the statute contains an exception, not applicable here, for certain waivers of coinsurance that are not advertised nor routine, and that are made on the basis of individualized determinations of financial hardship. See section 1128A(i)(6) of the Act.

The Waiver Policy may also implicate the anti-kickback statute. 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 Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services paid for 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. The OIG may also initiate administrative proceedings to exclude such parties from the Federal health care programs under section 1128(b)(7) of the Act or to impose civil monetary penalties under section 1128A(a)(7) of the Act.

B. Analysis

The Waiver Policy clearly comes within the general statutory prohibition against improper inducements to beneficiaries. The Hospital waives coinsurance for the Screening Services and Follow-Up Services in order to induce patients, including Medicare and Medicaid beneficiaries, to receive those services at the Center. Moreover, the Waiver Policy does not qualify for the preventive care exception, both because the Screening Services are sometimes tied to the delivery of certain non-preventive Follow-Up Services, which are also reimbursable under Medicare and Medicaid, and because the Waiver Policy applies to certain services that do not fit the regulatory definition of preventive care. Therefore, we must carefully scrutinize the facts and circumstances presented to assess the relative risks and benefits of the Waiver Policy.

Although we continue to have serious concerns regarding the waiver of coinsurance for screening services when the waiver is tied to other services reimbursable by Medicare or Medicaid, we conclude that, for the combination of reasons listed below, we will not impose administrative sanctions on the Hospital under the beneficiary inducement CMP at section 1128A(a)(5) of the Act nor will we impose administrative sanctions under sections 1128(b)(7) or 1128A(a)(7) of the Act (as they related to the anti-kickback statute) in connection with the Waiver Policy. Our analysis turns on two aspects of the Waiver Policy, which, taken together, substantially minimize any risk of fraud or abuse.

First, the large majority of patients benefited by the Waiver Policy are uninsured individuals, who might otherwise receive no screening services. While the costs of providing care to these patients are offset, in part, by Federal and state funds, they are also subsidized by private donations and by the Hospital. The receipt of services by some insured patients, including Medicare and Medicaid beneficiaries, does not alter the fundamental charitable nature of the endeavor. In short, given the uninsured status of the majority of patients receiving services, it is unlikely that the Screening Services, in conjunction with the Waiver Policy, will generate substantial remunerative services for the Hospital.

Second, although the Screening Services that would otherwise qualify for the preventive care exception are tied in some cases to non-qualifying services, the non-qualifying services are limited to those necessary to confirm the initial screening results. As such, application of the Waiver Policy to the Follow-Up Services merely effectuates the initial

Screening Services. Follow-up therapeutic services are neither covered by the Waiver Policy, nor typically rendered for Center patients by the Hospital.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Waiver Policy may potentially generate prohibited remuneration under the CMP for inducements to beneficiaries and 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 will not impose administrative sanctions on [name redacted] in connection with the Waiver Policy for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Act nor for violations of the anti-kickback statute 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).

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], who is 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 Waiver Policy.
- 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 Waiver Policy 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 Waiver Policy 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,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General