



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 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 requestor.]

Issued: December 27, 2012

Posted: January 3, 2013

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-21

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a Federally qualified health center's proposal to offer grocery store gift cards to certain patients in capitated managed care plans as an incentive to receive health screenings or other clinical services (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute 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 Proposed Arrangement would not constitute

grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Proposed 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”) would 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 Proposed Arrangement. This opinion is limited to the Proposed 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 “Health Center”) is a 501(c)(3) nonprofit community health center located in [city and state names redacted]. The Health Center participates in Medicare and State health care programs (including Medicaid) and receives Federal grants to deliver health care services as a Federally qualified health center.¹

As part of its Medicaid program, the State of [name redacted] (the “State”) has engaged local managed care plans to provide managed care services for reimbursement on a capitated basis. In turn, some of the managed care plans selected the Health Center to serve as a contracted provider for the managed care plans’ Medicaid enrollees and pay the Health Center for these services on a capitated basis. Each managed care plan assigns its enrollees to specific contracted providers (such as the Health Center) based on considerations including, but not limited to, the enrollees’ geographic location and family ties, and the contracted provider’s available capacity.

¹ Federally qualified health centers receive support pursuant to section 330 of the Public Health Services Act. All recipients of grants under section 330 are public, nonprofit, or tax-exempt entities. They must serve “a population that is medically underserved, or a special medically underserved population comprised of migratory and seasonal agricultural workers, the homeless, and residents of public housing.” Health Centers Consolidation Act of 1996 § 330(a)(1), 42 U.S.C. § 254b(a)(1) (2010). Consistent with their mission and the terms of their Public Health Service grants, section 330 grant recipients serve predominantly low-income individuals, including some beneficiaries of the Medicare and Medicaid programs. See Preamble to Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 72 Fed. Reg. 56,632, 56,633 (Oct. 4, 2007).

Ordinarily, an enrollee must affirmatively elect to obtain reassignment to a different contracted provider before such reassignment would occur. An enrollee's failure to use the Health Center's services would not affect his or her contracted provider assignment, nor would it diminish the payments received by the Health Center in connection with the enrollee.

Under the Proposed Arrangement, the Health Center would send letters to the enrollees of capitated Medicaid managed care plans who either: (1) were newly assigned to the Health Center as their contracted provider, or (2) were assigned to the Health Center as their contracted provider at least one year before and have not been seen by the Health Center in the past twelve months (collectively, the "Eligible Enrollees"). The letters would be sent to all Eligible Enrollees, regardless of the health status of any individual Eligible Enrollee.

The letters would offer the recipient Eligible Enrollee the opportunity to claim an incentive gift card redeemable for \$20 in groceries from a major supermarket chain (the "Gift Card") in exchange for a visit to the Health Center for a screening or any other clinical service performed on behalf of the Eligible Enrollee. Award of the Gift Card would not depend on the Eligible Enrollee's selection of any particular screening or other clinical service. The Gift Card would not be redeemable for cash or for items or services from the Health Center. The Proposed Arrangement limits an individual Eligible Enrollee to a single Gift Card offer during any given twelve-month period. The Gift Card would be presented along with educational materials on nutrition and health maintenance, as well as practical guidance for use of the Health Center. The Proposed Arrangement would not be advertised or marketed other than in the letters to Eligible Enrollees described above.

The Health Center certified that the Proposed Arrangement is intended: (1) to encourage patients to be seen for care and to be engaged in preventive care; (2) to encourage patients to learn more about the Health Center, their medical home; and (3) to help the Health Center achieve better health outcomes.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully 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. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), 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 offers or transfers remuneration 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 the CMP as including “transfers of items or services for free or for other than 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 in value” to mean “no more than \$10 per item, or \$50 in the aggregate on an annual basis.” 65 Fed. Reg. 24,400, 24,410–11 (Apr. 26, 2000) (preamble to the final rule on Civil Money Penalties).

The CMP 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 applicable 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 regulations define “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.

Under the Proposed Arrangement, the Gift Card would be given to any Eligible Enrollee who visited the Health Center for a screening or any other clinical service. Some of the resulting visits to the Health Center would likely meet the § 1003.101 definition of a preventive care service. The incentive could also be given, however, in connection with visits that fell outside that definition. As a result, the Proposed Arrangement would not satisfy the requirements of the preventive care exception to the CMP, and the exception would not protect the remuneration from the Health Center to the Eligible Enrollee in the form of the Gift Card.

B. Analysis

The Proposed Arrangement, under which the Health Center would provide an Eligible Enrollee a Gift Card redeemable for \$20 in groceries in exchange for a clinical visit to the Health Center, would implicate both the CMP and the anti-kickback statute.

Arrangements whereby a prospective provider or supplier of Federally payable items and services offers beneficiaries a non-covered item or service free of charge implicate the fraud and abuse laws and must be closely scrutinized.

As we have noted elsewhere, there are valid reasons for Congress's determination to restrict the availability of "giveaways" in connection with Medicare and Medicaid providers. First, such programs can corrupt the decision-making process, resulting, for example, in over-utilization, increased costs, or inappropriate medical choices. Second, there is potential harm to competing providers and suppliers who do not, or cannot afford to, offer incentives to generate business. Third, these practices could negatively affect the quality of care given to beneficiaries. As providers and suppliers race to the bottom by offering increasingly valuable goods or services, the incentive to offset the cost of these inducements by cheating on the quality of the Medicare or Medicaid item or service increases proportionately. See, generally, *OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries* (Aug. 2002), available at: <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

We begin with the application of the CMP to the facts presented. The Gift Card would clearly constitute remuneration to Federal health care program beneficiaries and would be of more than nominal value. We therefore consider whether this remuneration would be likely to influence beneficiaries to select the Health Center as their contracted provider of items and services payable by Medicare or Medicaid. We believe the answer is no for a combination of reasons. In the State, Medicaid beneficiaries are assigned by their managed care plan to a contracted provider on the basis of criteria including geographic location and family ties.

In order to select the Health Center as their contracted provider, Medicaid beneficiaries assigned to other contracted providers would first have to affirmatively elect to obtain reassignment. In addition, the Gift Card would be of relatively modest value and would

not be redeemable for cash, or for items or services provided by the Health Center. The offer of the Gift Card, moreover, would not be advertised or marketed, except to certain groups of beneficiaries already assigned to the Health Center. For these reasons, we believe that, in the overall context of the Proposed Arrangement, the Gift Card would have minimal influence over beneficiaries' selection of their contracted provider.

Having concluded that the Proposed Arrangement would be unlikely to influence beneficiaries to select the Health Center, it is not necessary to proceed to the third issue under the CMP (i.e., whether the Health Center knows, or should know, that the Proposed Arrangement would be likely to influence beneficiaries' selection of the Health Center for items and services). Accordingly, we conclude that the Health Center's offer of the Gift Card in this particular context would not be an impermissible inducement to obtain covered items and services under the CMP.

For the following reasons, in combination with the factors set forth above, we conclude that the Proposed Arrangement would pose a minimal risk of fraud and abuse under the anti-kickback statute and, therefore, we would not impose administrative sanctions under that statute on the Health Center in connection with the Proposed Arrangement.

First, under the Proposed Arrangement, the Health Center would offer the Gift Card only to Eligible Enrollees. All Eligible Enrollees would be enrolled in Medicaid managed care plans that are reimbursed on a capitated basis. Medicaid would not change the capitated payments made to the managed care plans based on the nature or number of services the Health Center provides to the Eligible Enrollees. The Health Center, in turn, would be compensated by the Medicaid managed care plans on a similarly capitated basis. Consequently, the Proposed Arrangement would not result in increased costs to the Federal health care programs, nor would the Health Center have an incentive to provide unnecessary care which might result in harm to beneficiaries.

Second, the Proposed Arrangement would not be advertised or marketed to the general public. Additionally, the Proposed Arrangement would limit the annual amount of incentives offered to an Eligible Enrollee to one Gift Card of relatively modest value. In a different context remuneration of such value could have a substantial potential to steer patients. Given the facts here, however, we regard the offer as unlikely to harm the Health Center's competitors or to result in a destructive race to the bottom among competing providers.

Consistent with the Health Center's not-for-profit mission, the Proposed Arrangement would provide a benefit to members of the largely poor and underserved community the Health Center serves. The Proposed Arrangement would have the apparent purpose of engaging beneficiaries and educating them about the Health Center and its potential role in the delivery of their health care, so as to both improve health outcomes and make best use of resources in connection with capitated managed care plans.

Although the Proposed Arrangement may implicate the Federal anti-kickback statute, in this particular context and for the same reasons noted above, we would not impose administrative sanctions arising in connection with the anti-kickback statute.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Proposed 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 would 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 Proposed Arrangement. This opinion is limited to the Proposed 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 by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- 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 Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) 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 Health Center with respect to any action that is part of the Proposed 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 Proposed 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 the Health Center with respect to any action that is part of the Proposed Arrangement 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General