



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, unless otherwise approved by the requestor(s).]

Issued: March 24, 2023

Posted: March 29, 2023

[Address block redacted]

Re: OIG Advisory Opinion No. 23-03

Dear [redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion on behalf of [redacted] (the “Parent”) and [redacted] (the “Laboratory,” and together with the Parent, “Requestors”), regarding their proposal to provide a prepaid card, such as a Visa or Mastercard gift card, of up to \$75 to certain individuals, including Federal health care program beneficiaries, to encourage those individuals to return the sample collection kit associated with Requestors’ colorectal cancer screening test (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the “Act”), as that section relates to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the “Beneficiary Inducements CMP”); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestors have certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Proposed Arrangement, and we have relied solely on the facts and information Requestors provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestors. This opinion is limited to the relevant facts presented to us by Requestors in connection with the Proposed Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent

were present, the OIG would not impose administrative sanctions on Requestors in connection with the Proposed Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) the Proposed Arrangement, if undertaken, would not constitute grounds for the imposition of administrative sanctions on Requestors in connection with the Proposed Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

This opinion may not be relied on by any person¹ other than Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

The Parent manufactures [redacted] (the “Test”), a proprietary, non-invasive colorectal cancer screening test that has been approved by the U.S. Food and Drug Administration (“FDA”). Requestors certified that the Test is the first and only FDA-approved non-invasive stool-based DNA colorectal cancer screening test available to patients who are at average risk for developing colorectal cancer. The Test is performed by the Parent’s wholly owned subsidiary, the Laboratory, and is the only laboratory that performs the Test.

Medicare covers the Test under specified circumstances. In October 2014, the Centers for Medicare & Medicaid Services (“CMS”) issued a Medicare National Coverage Determination and supporting Decision Memorandum stating that Medicare Part B will cover the Test once every 3 years for Medicare beneficiaries aged 50 or older who meet certain criteria.² In November 2022, CMS revised its coverage determination for colorectal cancer screening, reducing the age from 50 to 45.³ In the same rulemaking revising its coverage determination, CMS stated:

[Colorectal cancer] screening presents a unique scenario where there are significant differences between screening stool-based tests and screening colonoscopy tests in terms of invasiveness and burdens to the patient and healthcare system. [CMS has] recognized there are several advantages to choosing a non-invasive stool-based [colorectal cancer] screening test as a first

¹ We use “person” herein to include persons, as referenced in the Federal anti-kickback statute and Beneficiary Inducements CMP, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

² [redacted]

³ Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID–19 Interim Final Rules, 87 Fed. Reg. 69,404, 69,764 (Nov. 18, 2022), <https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf>.

step compared to a screening colonoscopy, including relative ease of administering the test and potentially reducing the experience of unnecessary burdensome preparation and invasive procedures. [CMS has] discussed that it has been reported that a large proportion (46 percent) of screening colonoscopies found no polyps so optimizing use of a non-invasive stool-based screening test as a first step (when determined appropriate by the patient and their healthcare professional) would benefit the patient and also the Medicare program. In many instances, a colonoscopy is not the most appropriate first step in colorectal cancer screening and would represent an unnecessary burden and over-servicing for both the patient and healthcare system.⁴

Requestors certified that, as of January 2023, under Medicare’s Clinical Laboratory Fee Schedule, the Laboratory is reimbursed approximately \$500 for each Test it performs.

In June 2016, the U.S. Preventive Services Task Force (“USPSTF”) issued a final recommendation designating stool-based DNA colorectal cancer screening as a recommended preventive care service and identified the Test as the only screening test of this type offered in the United States.⁵ For all adults aged 45 to 75 years, the USPSTF recommends the Test every 1 to 3 years.⁶ In addition, the Test is one of six screening tests recommended in the American Cancer Society Colorectal Cancer Prevention and Early Detection guide to detect cancer in individuals at average risk for developing colorectal cancer.⁷

⁴ Id. at 69,764-69,765 (internal citations omitted).

⁵ The USPSTF has designated colorectal cancer screening, including with the Test, as a grade “A” recommendation for patients aged 50-75, a grade “B” recommendation for patients aged 45-49, and a grade “C” recommendation for patients aged 76-85. USPSTF, Final Recommendation Statement, Colorectal Cancer: Screening (May 18, 2021), <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening> (the “USPSTF Recommendation Statement”). A grade “A” designation means that the “USPSTF recommends the service [and] there is high certainty that the net benefit is substantial.” A grade “B” designation means that the “USPSTF recommends the service [and] there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.” A grade “C” designation means the “USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences [and] [t]here is at least moderate certainty that the net benefit is small.” USPSTF, Grade Definitions, <https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/grade-definitions>.

⁶ USPSTF Recommendation Statement.

⁷ American Cancer Society, Colorectal Cancer Prevention and Early Detection, <http://www.cancer.org/acs/groups/cid/documents/webcontent/003170-pdf.pdf>.

The Test may be ordered for a patient only by health care providers acting within the scope of their prescribing authority (each, a “Prescriber”). After the Prescriber submits an order for the Test to the Laboratory, the Laboratory ships the Test sample collection kit⁸ directly to the patient’s home. The patient subsequently collects their own stool sample and ships the Test collection kit with the stool sample (the “Kit”) to the Laboratory in a prepaid, preaddressed package. The Laboratory then analyzes the stool sample and compares the composite score of the various assay results to a control to determine a positive or negative result. A positive result may indicate the presence of colorectal cancer or advanced adenoma and should be followed by a diagnostic colonoscopy.

Requestors generally contact a patient upon receiving the Prescriber’s order for the Test to verify the patient’s address, encourage the patient to contact the Laboratory with any questions about the Test, and request that the patient promptly return the Kit. If the Laboratory has not received a patient’s Kit in a timely manner, Requestors remind the patient to return the Kit at least once by way of automated phone calls, non-automated phone calls, text messages, emails, letters, or through multiple communication media. Requestors certified that their data show that more than 30 percent of patients fail to return the Kit back to the Laboratory for analysis. Therefore, Requestors intend to implement the Proposed Arrangement to encourage patients to return the Kit, thereby promoting patient compliance with the Prescriber’s order for the Test.

Under the Proposed Arrangement, if the Laboratory has not received the Kit following at least two patient contacts, Requestors would send the patient a reminder letter (the “Letter”) no sooner than 2 weeks, and no later than 180 days, after the patient receives the Test sample collection kit. The Letter would include a telephone number the patient can call with any questions. Unlike the first two patient contacts, the Letter also would state that, if the patient returns the Kit within the period of time specified in the Letter,⁹ Requestors would send the patient a prepaid card, such as

⁸ The Test sample collection kit contains patient instructions, a protein sample tube with a stool collection stick and buffer, a stool collection container, a foldable plastic bracket, a liquid preservative, and a mailing container.

⁹ The return period offered to any individual patient would not be based on any characteristics specific to that patient (*i.e.*, age, demographics, or payor) or specific to the Prescriber. Requestors certified that Gift Cards would not be provided to those patients who return their Kits after the deadline specified in the Letter.

a Visa or Mastercard gift card, with a value of up to \$75 (the “Gift Card”).¹⁰ The Gift Card would not be redeemable for or convertible into cash and would be non-reloadable.¹¹

Requestors certified they would implement certain safeguards related to the Proposed Arrangement. In particular, Requestors certified that:

- The Gift Card would be mailed only to those patients who return the Kit by the deadline specified in the Letter.
- They would advise patients in the Letter that the Gift Card may not be used for items or services provided by Requestors.
- Each patient would be limited to receiving one Gift Card per 36-month period, a time period that aligns with Medicare’s coverage for the Test, which is once every 36 months.¹²
- Requestors would implement processes to ensure that the recipient of the Gift Card had not already received a Gift Card in the prior 36-month period.
- Apart from the Letter,¹³ Requestors would not engage in any patient-focused promotion of the Proposed Arrangement, such as direct-to-consumer advertisements on third-party websites or advertisements in newspapers, on television or radio, or in magazines in connection with the Proposed Arrangement.
- Requestors would not advertise or market the Proposed Arrangement to Prescribers or offer or pay any remuneration to Prescribers in connection with the Proposed Arrangement.

¹⁰ The Gift Card may be for a lower amount than \$75 but would not exceed \$75. Requestors certified that they would determine the lowest amount less than or equal to \$75 that significantly improves patient compliance with returning the Kit and would thereafter only offer the minimum denomination possible (less than or equal to \$75) to ensure compliance. Requestors certified that they would not vary the value of any Gift Card offered or provided to any particular patient based on any characteristics specific to that patient (i.e., age, demographics, payor) or specific to the Prescriber.

¹¹ The Gift Card would not be operational at an ATM to withdraw cash or with a vendor to obtain cash back after a purchase (and the Gift Card could not be used with a vendor that accepts only cash).

¹² [redacted]

¹³ Requestors certified that they may send patients an additional letter, which also would mention the Gift Card, that would similarly remind patients to return the Kit to the Laboratory within the period of time specified in the Letter.

- The Proposed Arrangement would not apply where the Test is ordered by Prescribers arranged for through Requestors’ website.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.¹⁴ The statute’s prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.¹⁵ For purposes of the Federal 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 is to induce referrals for items or services reimbursable by a Federal health care program.¹⁶ Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

2. Beneficiary Inducements CMP

The Beneficiary Inducements 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 beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines “remuneration” for

¹⁴ Section 1128B(b) of the Act.

¹⁵ Id.

¹⁶ E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); 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).

purposes of the Beneficiary Inducements CMP as including “transfers of items or services for free or for other than fair market value.”

Section 1128A(i)(6) of the Act contains an exception to the definition of “remuneration” that may apply in the context of the Proposed Arrangement. Specifically, section 1128A(i)(6)(D) of the Act excludes incentives given to individuals to promote the delivery of preventive care from the definition of “remuneration” for purposes of the Beneficiary Inducements CMP (the “Preventive Care Exception”). The regulations interpreting the Preventive Care Exception 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, but may not include . . . [c]ash or instruments convertible to cash; or . . . [a]n incentive the value of which is disproportionately large in relationship to the value of the preventive care service¹⁷

The regulations define “preventive care” to include any service that is a specific clinical service “described in the current [USPSTF’s] Guide to Clinical Preventive Services”¹⁸ and is reimbursable by Medicare or an applicable State health care program.¹⁹

¹⁷ 42 C.F.R. § 1003.110. We note the regulatory text of the Preventive Care Exception uses the term “instruments convertible to cash” as opposed to “cash equivalents.” 42 C.F.R. § 1003.110; 65 Fed. Reg. 24,000, 24,409 (Apr. 26, 2000). In subsequent guidance we stated that “cash equivalents” are “items convertible to cash (such as a check) or that can be used like cash (such as a general purpose debit card, but not a gift card that can be redeemed only at certain stores or for a certain purpose, like a gasoline gift card).” 81 Fed. Reg. 88,368, 88,393 n.19 (Dec. 7, 2016). We are taking this opportunity to clarify that that the phrase “instruments convertible to cash” refers to a subset of “cash equivalents.” “Cash equivalents” include a broader range of remuneration. OIG would consider a prepaid card, such as a Visa or Mastercard gift card, to be a “cash equivalent” but not an “instrument convertible to cash.”

¹⁸ We note that the Preventive Care Exception refers to the USPSTF’s Guide to Clinical Preventive Services, which has not been published or updated since 2014, while the USPSTF website provides the USPSTF’s most current published recommendations. Therefore, for the purposes of this exception, we interpret the regulation’s reference to the USPSTF’s Guide to Clinical Preventive Services to include the final published recommendations by the USPSTF on its website. See https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results?topic_status=P.

¹⁹ 42 C.F.R. § 1003.110.

B. Analysis

Under the Proposed Arrangement, Requestors would provide a Gift Card to patients who have not yet returned a completed Kit to the Laboratory to encourage such patients to return the Kit to the Laboratory for testing that could be reimbursed by Federal health care programs. Thus, the Proposed Arrangement would implicate the Beneficiary Inducements CMP because Requestors would offer and transfer remuneration (the Gift Card) to patients eligible for Medicare or State health care programs, and Requestors should know that the Gift Card would be likely to influence such individuals to receive a reimbursable service from the Laboratory (given that the Laboratory is the only laboratory that performs the Test). In addition, the Proposed Arrangement would implicate the Federal anti-kickback statute because Requestors would offer and pay remuneration (the Gift Card) in an attempt to induce a patient to return the Kit to the Laboratory, resulting in the purchase of the laboratory services in connection with the Test, which are reimbursable by Federal health care programs. We first analyze the Proposed Arrangement under the Beneficiary Inducements CMP and assess whether an exception applies.

1. Beneficiary Inducements CMP

The Proposed Arrangement would not subject Requestors to sanctions under the Beneficiary Inducements CMP because the offer and transfer of the Gift Card to patients by Requestors would satisfy the requirements of an exception to the definition of “remuneration” under the Beneficiary Inducements CMP: the Preventive Care Exception. The Gift Card under the Proposed Arrangement would satisfy this exception because, first, Requestors would offer and transfer Gift Cards to individuals eligible for Medicare and State health care programs to promote the delivery of the laboratory services in connection with the Test, a specific clinical service described in the current USPSTF’s Guide to Clinical Preventive Services. Second, the Gift Card would neither be an instrument convertible to cash, nor, in this particular case, disproportionately large in relationship to the value of the preventive care service.²⁰ Finally, although the Test may result in individuals eligible for Medicare and State health care programs obtaining additional services, like a colonoscopy (as clinically appropriate), the Test would not be tied, directly or indirectly, to the provision of those additional services. Accordingly, the Gift Card would not constitute remuneration under the Beneficiary Inducements CMP.

2. Federal Anti-Kickback Statute

Although we conclude the Gift Card furnished through the Proposed Arrangement would not constitute remuneration under the Beneficiary Inducements CMP, such a conclusion does not mean that the Gift Card under the Proposed Arrangement would not constitute remuneration

²⁰ Requestors certified that Medicare reimburses the Test at approximately \$500. However, for the purposes of the Preventive Care Exception, we view “value” as broader than the Medicare reimbursement amount, to include (i) factors such as potential benefits to a beneficiary, or (ii) the future health care costs reasonably expected to be avoided as a result of the preventive care. Thus, it is possible that, with a different set of facts, an incentive with a value of up to \$75 would be disproportionately large in relationship to a preventive care service reimbursed at approximately \$500.

under the Federal anti-kickback statute, nor does it automatically render the Proposed Arrangement low risk under the Federal anti-kickback statute. As a threshold matter, we note that OIG has long-standing concerns about remuneration that could: (i) influence a beneficiary's choice of a provider, supplier, item, or service; (ii) create incentives for providers and suppliers to offset the additional costs attributable to any remuneration given to beneficiaries by providing unnecessary or subpar service; or (iii) favor providers and suppliers with greater financial resources over smaller entities. With regard to preventive care services, we have noted that:

From an anti-kickback perspective, the chief concern is whether an arrangement to induce patients to obtain preventive care services is intended to induce other business payable by a Federal health care program. Relevant factors in making this evaluation would include, but not be limited to: the nature and scope of the preventive care services; whether the preventive care services are tied directly or indirectly to the provision of other items or services and, if so, the nature and scope of the other services; the basis on which patients are selected to receive the free or discounted services; and whether the patient is able to afford the services.²¹

For the reasons set forth above and below, we conclude that the Proposed Arrangement presents a minimal risk of fraud and abuse under the Federal anti-kickback statute.

First, the Proposed Arrangement is unlikely to lead to improperly increased costs to Federal health care programs or overutilization of federally reimbursable services. The USPSTF recommends the Test every 1 to 3 years for all adults aged 45 to 75 years, and Medicare covers the Test only by prescription once every 36 months. Requestors would offer and provide the Gift Card only once per 36-month period regardless of whether the Test is ordered more than once during the 36-month timeframe. Because Requestors would not offer any incentives to Prescribers in connection with the Proposed Arrangement, and a Prescriber would not be able to anticipate whether Requestors would offer or provide a Gift Card to any patient for whom the Prescriber orders the Test, the Proposed Arrangement is unlikely to influence a Prescriber to order the Test in lieu of not ordering a test or ordering another screening test or procedure. Moreover, the Test is reimbursed at a fixed rate under the Clinical Laboratory Fee Schedule regardless of whether the Gift Card is provided to a patient, thus precluding Requestors from inappropriately increasing costs to Federal health care programs by passing on the costs associated with the Gift Cards, directly or indirectly, to those programs.

Second, the Proposed Arrangement would promote patient compliance with a screening test that has been recommended by the USPSTF and the American Cancer Society to screen for colon cancer and that CMS has said “would benefit the patient and also the Medicare program.”²² Requestors certified that more than 30 percent of patients fail to return the Kit to the Laboratory for analysis, and the Gift Card would be provided only to those individuals who do not return the Kit after at least three reminders (including the Letter) and within a specified period of time and

²¹ OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4873 (Jan. 31, 2005), <https://www.govinfo.gov/content/pkg/FR-2005-01-31/pdf/05-1620.pdf>.

²² 87 Fed. Reg. at 69,764.

who, therefore, might not otherwise comply with a Prescriber’s order for the Test. Further, we recognize the collection of the specimen by patients for this particular test—which requires patient interaction with their stool as opposed to a test requiring only saliva collection, for example—may be of a type where the Gift Card would be necessary to encourage some patients to return the Kit.²³

Lastly, the Proposed Arrangement contains several other safeguards that reduce the risk of fraud and abuse. For example, (i) Requestors would implement processes to ensure that no patient would be offered or provided a Gift Card if the patient had received a Gift Card in the prior 36-month period; (ii) apart from the Letter, Requestors would not engage in any patient-focused promotion of the Proposed Arrangement, such as direct-to-consumer advertisements on third-party websites or advertisements in newspapers, on television or radio, or in magazines in connection with the Proposed Arrangement; (iii) the Proposed Arrangement would not be advertised or marketed to Prescribers, nor would Requestors offer or pay any remuneration to Prescribers in connection with the Proposed Arrangement; and (iv) the Proposed Arrangement would not apply where the Test is ordered by Prescribers arranged for through Requestors’ website. These safeguards, in combination with all of the other factors already discussed, evidence that the Proposed Arrangement would provide an incentive to encourage legitimate cancer screening services, and likely would not encourage medically unnecessary services or improper utilization of the Test.

We appreciate that the Gift Card may present the opportunity for patients to receive valuable remuneration that could induce them to purchase federally reimbursable services and caution that if any of the foregoing facts were different, we likely would reach a different conclusion with respect to the risk presented by this type of arrangement under the Federal anti-kickback statute, regardless of whether the arrangement satisfies an exception to the Beneficiary Inducement CMP.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG would not impose administrative sanctions on Requestors in connection with the Proposed Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) the Proposed Arrangement, if undertaken, would not constitute grounds for the imposition of administrative sanctions on Requestors in connection with the Proposed Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

²³ The USPSTF recognizes that “stool-based screening requires persons to collect samples directly from their feces, which may be unpleasant for some, but the test is quick and noninvasive” USPSTF Recommendation Statement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.
- This advisory opinion is issued only to Requestors. This advisory opinion has no application to, and cannot be relied upon by, any other person.
- This advisory opinion may not be introduced into evidence by a person other than Requestors to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion 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.
- We express no opinion herein regarding the liability of any person 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 Requestors 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 Requestors 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,

/Susan E. Gillin/

Susan E. Gillin
Acting Assistant Inspector General for Legal
Affairs