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: November 7, 2013

Posted: November 14, 2013

[Name and address redacted]

Re: OIG Advisory Opinion No. 13-16

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a health insurer's proposal to pay the Medicare Part B premium costs for Medicare-eligible individuals with End-Stage Renal Disease ("ESRD") who are enrolled in a group health plan offered by the insurer and receiving dialysis 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

A. ESRD and Medicare Payment Provisions

ESRD is a chronic disease that requires regular dialysis, as well as monitoring of laboratory values, diet, and medication. Individuals with ESRD who have earned a certain level of eligibility for Social Security benefits (or who are dependents of those who have attained that level) are eligible, but not required, to enroll in Medicare Part B.[1] Medicare Part B covers outpatient maintenance dialysis treatments when they are provided to an ESRD patient by an approved ESRD facility, such as an independent dialysis facility.[2]

Outpatient maintenance dialysis treatments furnished to Medicare beneficiaries in an approved ESRD facility are reimbursed under a case-mix adjusted bundled prospective

[1] See section 226A of the Act.

[2] See Medicare Benefit Policy Manual, Centers for Medicare & Medicaid Services ("CMS") Pub. 100-02, Chapter 11, Section 20.

payment system ("ESRD PPS").[3] The ESRD PPS payment amounts are subject to the normal Part B deductible and coinsurance requirements.

Medicare is secondary payor to group health plans for individuals who are eligible for or entitled to Medicare benefits based on ESRD during a coordination period of up to 30 months (the "Coordination Period") if Medicare was not the proper primary payor for the individual based on age or disability at the time the individual became eligible for or entitled to Medicare on the basis of ESRD.[4] The Medicare secondary payor provisions apply to all Medicare-covered items and services furnished to beneficiaries who are in the Coordination Period, including services for non-ESRD treatment.[5]

B. Background Information and Current Benefit Plan Design

[Name redacted] (the "Requestor") provides commercial health insurance products to individuals, families, and group health plans ("Commercial Products") in the State of [state name redacted]. In general, the amount the Requestor reimburses a particular provider, supplier, or practitioner (collectively, "providers") for services furnished to individuals enrolled in a Commercial Product ("Commercial Enrollees") varies depending on whether or not the Requestor and the provider have entered into a participating provider agreement ("PPA"), the terms of the PPA, and the Commercial Product benefit design.

In cases in which a provider that has entered into a PPA with the Requestor (a "Participating Provider") furnishes services to a Commercial Enrollee, the Participating Provider's reimbursement amount for the service (the "Allowed Amount") is determined

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[3] See Medicare Program; End-Stage Renal Disease Prospective Payment System, 75 Fed. Reg. 49,029 (Aug. 12, 2010). The ESRD PPS final rule became effective January 1, 2011, replacing the previously effective basic case-mix adjusted composite payment system and methodologies for the reimbursement of separately billable outpatient ESRD services. The ESRD PPS final rule provides for a four-year transition period, with all facilities transitioned to the ESRD PPS on January 1, 2014.

[4] See section 1862(b)(1)(C) of the Act; Medicare Secondary Payer Manual ("MSPM"), CMS Pub. 100-05, Chapter 1, Section 10.2, and Chapter 2, Section 20. When Medicare is the secondary payor, the provider, physician, or other supplier, or beneficiary must first submit the claim to the primary payor. The primary payor is required to process and make primary payment on the claim in accordance with the coverage provisions of its contract. See MSPM, CMS Pub. 100-05, Chapter 1, Section 10.

[5] See MSPM, CMS Pub. 100-05, Chapter 1, Section 10.2.

by the terms and conditions of the PPA.[6] For example, where a Commercial Enrollee with ESRD receives dialysis treatments from a dialysis center that is a Participating Provider (a "Participating Dialysis Center"), the PPA determines the Allowed Amount. The Requestor certified that its Commercial Product benefit designs typically require it to pay 80 percent of a Participating Dialysis Center's Allowed Amount, with the Commercial Enrollee responsible for the remaining 20 percent, subject to the out-of-pocket maximum. Thus, if the Allowed Amount for dialysis treatments provided by a Participating Dialysis Center is $14,000 per month—which the Requestor certified is typical—then the Requestor would pay the provider $11,200, and the Commercial Enrollee would owe $2,800.

In cases in which a dialysis center that has not entered into a PPA with the Requestor (a "Non-Participating Dialysis Center") furnishes services to a Commercial Enrollee, the amount the Requestor must reimburse the provider is determined by the terms and conditions of the relevant Commercial Product benefit design. The Requestor states that a typical Commercial Product benefit design requires it to pay 60 percent of the total reimbursement amount Requestor set for the service, with the Commercial Enrollee responsible for both the remaining 40 percent and the difference between the total reimbursement amount Requestor set for the service and the amount the Non-Participating Dialysis Center billed for the service. In certain non-competitive areas (i.e., geographical areas in which the vast majority of Commercial Enrollees have reasonable access only to Non-Participating Dialysis Centers), the Requestor set the total reimbursement amount for dialysis services at 90 percent of the Non-Participating Dialysis Center's billed charges. Thus, if a Non-Participating Dialysis Center in a non-competitive area bills $50,000 per month for dialysis treatments—which the Requestor certified is typical—then the Requestor would pay $27,000.[7] The Requestor certified that the Commercial Enrollee then would be responsible for the difference between the Non-Participating Dialysis Center's billed charges and the amount reimbursed by the Requestor, or $23,000.

C. The Requestor's Proposed Modified Benefit Design

The Requestor wishes to modify its Commercial Product benefit design for group health plans to reduce the disparity between the amounts it reimburses Participating Dialysis Centers and Non-Participating Dialysis Centers. Under the Requestor's proposed

[6] The amount the Requestor must reimburse a Participating Provider is calculated as: (the Allowed Amount) x (the benefit level set forth in the Commercial Product benefit design), subject to rules regarding the out-of-pocket maximum. The remaining portion of the Allowed Amount is owed by the Commercial Enrollee.

[7] The Requestor's reimbursement obligation is calculated as: $50,000 x 90% x 60%.

modified benefit design (the "Proposed Modified Benefit Design"), the Requestor no longer would pay Non-Participating Dialysis Centers an amount tied to their billed charges for dialysis treatment services provided to group health plan Commercial Enrollees ("Group Enrollees"). Rather, the Requestor would set the total reimbursement level for dialysis services provided by Non-Participating Dialysis Centers at a new amount, such that the amount the Requestor would be required to pay would equal or exceed the ESRD PPS amount.[8] The Requestor further certified that, for 2012, the typical monthly ESRD PPS reimbursement amount for dialysis treatments was approximately $3,100.

Under the Requestor's Proposed Modified Benefit Design, the Requestor's costs for dialysis treatments provided by Non-Participating Dialysis Centers to Group Enrollees would decrease significantly, from approximately $27,000 to approximately $3,500 per Group Enrollee per month. However, the costs to Group Enrollees who are not enrolled in Medicare would increase significantly, from approximately $23,000 to approximately $46,500[9] per month. Neither the Requestor's costs nor the costs for Group Enrollees who are not enrolled in Medicare for dialysis treatments provided by Participating Dialysis Centers would change under the Proposed Modified Benefit Design.

D. Impact of Medicare Enrollment

If a Group Enrollee enrolled in Medicare Part B and the Requestor implemented the Proposed Modified Benefit Design, then, under Medicare's coordination of benefits rules, the Requestor would be the primary payor and Medicare would be the secondary payor with respect to health care services furnished to that Group Enrollee during the Coordination Period. After the expiration of the Coordination Period, Medicare would become the primary payor even though the Group Enrollee might continue to receive

[8] The ESRD PPS amount paid to an individual ESRD facility may vary based on a number of adjustments for case-mix variables, high cost outlier payments, and other factors. The Requestor certified that, to ensure that its reimbursement amount will equal or exceed the ESRD PPS amount, it purchased industry-accepted ESRD pricing software. The Requestor states that the software vendor works closely with CMS to ensure that its software replicates Medicare ESRD reimbursement parameters. The Requestor further certified that, in the unlikely event of a pricing error, it would manage any resulting appeals and make any additional payments required to bring its total net payment amount to an amount that equals or exceeds the ESRD PPS amount.

[9] The Group Enrollee copayment amount is calculated as the Non-Participating Dialysis Center's billed amount of $50,000, less the Requestor's approximated reimbursement amount under the Proposed Modified Benefit Design of $3,500.

coverage through one of the Requestor's group health plan Commercial Products by reason of employment or other status.[10]

During the Coordination Period, any amounts due for dialysis services from Medicare and Group Enrollees to dialysis centers that participate in Medicare and accept assignment effectively would be tied to or capped by Medicare's allowable reimbursement amounts for the services at issue. For example, if the monthly ESRD PPS reimbursement amount for dialysis treatments was $3,100 and the Requestor, acting as the primary payor, already had reimbursed a dialysis center in excess of that amount, the dialysis center would not be entitled to any additional payment either from Medicare, acting as the secondary payor,[11] or from the Group Enrollee.[12] Once the Coordination Period expires and Medicare becomes the primary payor, dialysis centers that participate in Medicare would be required to accept the ESRD PPS reimbursement amount as payment in full.[13]

E. The Proposed Arrangement

The Requestor certified that it was informed by [state name redacted] State Office of the Insurance Commissioner ("State Office") personnel that the State Office likely would not approve the Proposed Modified Benefit Design unless the Group Enrollees with ESRD who would be negatively impacted by the Proposed Modified Benefit Design's increased copayment amounts had Medicare coverage. The Requestor also stated that State Office personnel expressed concern that these Group Enrollees might not be able to afford the Medicare Part B premiums.

Under the Proposed Arrangement, the Requestor would offer to pay the Medicare Part B premiums for every Group Enrollee with ESRD who qualifies for, and wishes to enroll in, Medicare, regardless of whether the Group Enrollee uses a Participating Dialysis Center or a Non-Participating Dialysis Center, or whether the Group Enrollee uses any particular provider, supplier, or practitioner for any other items or services. Upon implementation of the Proposed Arrangement, the Requestor would mail letters to all Group Enrollees who are dialyzing (i.e., for whom the Requestor received dialysis claims). For existing Group Enrollees who already are enrolled in Medicare Part B, the Requestor would inform them that it would begin paying for their Part B premiums. For

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[10] See section 1862(b)(1)(C) of the Act; 42 C.F.R. § 411.162.

[11] See 42 C.F.R. § 411.33(e).

[12] See 42 C.F.R. § 411.35(c).

[13] See section 1881(b)(2)(A) of the Act; 42 C.F.R § 413.172(b).

existing Group Enrollees who are not enrolled in Medicare Part B, the Requestor would encourage them to enroll in Medicare Part B by informing them that it would pay their premiums. With regard to new Group Enrollees, the Requestor would run monthly claims reports to identify any new dialyzing Group Enrollees, and then would engage in the outreach described above. Communications to Group Enrollees initially would be by means of a letter. The Requestor's clinical team would follow up with phone calls to educate Group Enrollees about Participating Dialysis Centers and Part B coverage. The Requestor certified that in no case would it pressure, require, or otherwise unduly influence or coerce Group Enrollees with ESRD to enroll in Medicare Part B. The Requestor also certified that, upon implementation of the Proposed Arrangement, it would not encourage Group Enrollees either to continue to use, or to switch to, Non-Participating Dialysis Centers.

Finally, the Requestor certified that the Proposed Arrangement is not designed or intended to increase or maintain plan enrollment as the Requestor would benefit financially if: (i) no individuals with ESRD enrolled in the Requestor's Commercial Products in the first instance, and (ii) existing Commercial Enrollees with ESRD disenrolled.

Based upon its communications with State Office personnel, the Requestor believes that the State Office would support the Proposed Modified Benefit Design as implemented under the Proposed Arrangement.

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 section 1128A(a)(5) as including "transfers of items or services for free or for other than fair market value."

B. Analysis

Under the Proposed Arrangement, the Requestor would offer or pay remuneration, in the form of Medicare Part B premium subsidies, to Group Enrollees with ESRD who are eligible for, and wish to enroll in, Medicare Part B. Thus, we must examine the Proposed Arrangement under both the CMP, to determine whether such remuneration would be likely to influence Group Enrollees with ESRD to order items or services from a particular provider, practitioner, or supplier, and the anti-kickback statute.[14] This opinion is limited to the narrow question of whether the Requestor's payment of Medicare Part B premium subsidies under the Proposed Arrangement implicates the CMP or the anti-kickback statute. We are not opining on the Requestor's current benefit plan design or the Proposed Modified Benefit Design. We address each issue in turn.

[14] We express no opinion regarding whether the Proposed Arrangement would violate: (1) CMS's regulations at 42 C.F.R. § 411.102(a)(1)(i), which prohibits a group health plan from taking into account the ESRD-based Medicare eligibility or entitlement of any individual who is covered or seeks to be covered under the plan, and 42 C.F.R. § 411.102(a)(1)(ii), which prohibits a group health plan from differentiating in the benefits it provides between individuals with ESRD and other individuals covered under the plan, on the basis of the existence of ESRD, or the need for dialysis, or in any other manner; or (2) the Medicare Secondary Payer provisions at section 1862(b) of the Act, as amended, or its implementing regulations.

1. The CMP

When analyzing arrangements under the CMP, the OIG historically has differentiated between incentives offered to Federal health care program beneficiaries to enroll in a plan, and incentives offered to beneficiaries to use a particular provider, practitioner, or supplier. Specifically, in the preamble to the final rule on civil money penalties, we stated:

> [H]ealth plans that provide incentives to Federal health care program beneficiaries to enroll in a plan are not offering remuneration to induce the enrollees to use a particular provider, practitioner, or supplier…However, incentives provided by health plans to induce a Federal health care program beneficiary to use a particular provider, practitioner, or supplier once the beneficiary has enrolled in a plan are within the purview of [the CMP] and are prohibited if they do not meet an exception.[15]

The Proposed Arrangement clearly is intended to influence Group Enrollees with ESRD to enroll in Medicare Part B; indeed, the subsidy is contingent on such enrollment. The question, therefore, is whether the subsidy would be likely to influence Group Enrollees with ESRD to order or receive any items or services from a particular provider, practitioner, or supplier. We conclude that it would not.

The Requestor certified that the Medicare Part B premium subsidy would be offered to every Group Enrollee with ESRD who is eligible for Medicare, regardless of whether the Group Enrollee uses a Participating Dialysis Center or a Non-Participating Dialysis Center, or whether the Group Enrollee uses any particular provider, supplier, or practitioner for any other items or services. Thus, the offer of the premium subsidy is not contingent on the Group Enrollee obtaining dialysis services (or any other services) from a particular provider.[16] Moreover, because the Requestor would identify Group Enrollees

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[15] See 65 Fed. Reg. 24,400, 24,407 (Apr. 26, 2000).

[16] This factor is in contrast to the circumstances under consideration in the May 2000 proposed rule for a new safe harbor to the CMP. See Medicare and State Health Care Programs: Fraud and Abuse; Civil Money Penalty Safe Harbor to Protect Payment of Medicare Supplemental Insurance and Medigap Premiums for ESRD Beneficiaries, 65 Fed. Reg. 25,460 (May 2, 2000). That proposed safe harbor would have provided protection to independent dialysis facilities that paid, in whole or in part, Medicare Part B premiums or Medicare Supplemental Health Insurance policy premiums for needy Medicare beneficiaries with ESRD. OIG withdrew this proposed rule because, among other reasons, we believed such a safe harbor would promote the very conduct the statute prohibits: offering remuneration to influence the selection of a particular provider. See

as eligible for the premium subsidy based on the Requestor's receipt of dialysis claims, any Group Enrollees who would receive the subsidy likely already would be receiving dialysis services from a provider of their choice. For these reasons, the payment of the Medicare Part B premium subsidy is unlikely to influence a Group Enrollee with ESRD to receive dialysis services from a particular provider. Furthermore, based on the Requestor's certifications, the universe of potentially attractive dialysis services providers would expand, rather than contract, under the Proposed Arrangement, because the Group Enrollees' copayments would be $0.00 regardless of whether they obtain dialysis services from a Participating Dialysis Center or a Non-Participating Dialysis Center. Consequently, Group Enrollees who previously were limited to Participating Dialysis Centers due to the lower copayments associated with them now would be free to choose either a Participating Dialysis Center or a Non-Participating Dialysis Center.

2. The Anti-Kickback Statute

The anti-kickback statute is implicated if an individual or entity "offers or pays any remuneration…to any person to induce such person to purchase…any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." Under the Proposed Arrangement, the Requestor would pay remuneration, in the form of the Medicare Part B premium subsidies, to Group Enrollees with ESRD to induce those individuals to enroll in Medicare Part B. Services become payable by a Federal health care program upon an individual's enrollment in that program. Because the Group Enrollees with ESRD would, by virtue of their condition, purchase goods and services (including dialysis services) payable by Medicare once they enrolled in Medicare Part B, the Proposed Arrangement would implicate the anti-kickback statute. We therefore must analyze the totality of facts and circumstances to determine whether the Proposed Arrangement presents more than a minimal risk of fraud and abuse.

We recognize that the Proposed Arrangement likely would result in increased costs to the Medicare program, particularly once the Coordination Period expires and Medicare becomes the primary payor. However, any increased costs to the Medicare program would result from a Group Enrollee's decision to enroll in Medicare Part B—an entitlement program for which the Group Enrollee with ESRD qualifies.

Bearing in mind that Group Enrollees with ESRD are entitled to Medicare benefits, for a combination of the following reasons, we conclude that the Proposed Arrangement presents a minimal risk of fraud and abuse.

Medicare and State Health Care Programs: Fraud and Abuse; Civil Money Penalty Exception to Protect Payment of Medicare Supplemental Insurance and Medigap Premiums for ESRD Beneficiaries, 67 Fed. Reg. 72,896, 72,897 (Dec. 9, 2002).

First, the Requestor certified that it would offer the premium subsidy to Group Enrollees for whom it receives dialysis claims. Because the population eligible for the premium subsidy is already dialyzing, the Proposed Arrangement is unlikely to result in increased utilization of dialysis services. In other words, the premium subsidies are unlikely to induce the Group Enrollees to receive dialysis services they would not otherwise have obtained.

Second, the Requestor certified that, under the Proposed Modified Benefit Design, it would pay Non-Participating Dialysis Centers an amount that would equal or exceed the ESRD PPS amount, thereby ensuring that the Medicare program would not incur any costs for the Group Enrollees' dialysis services during the Coordination Period.

Third, the Requestor certified that the subsidy it would offer under the Proposed Arrangement would be offered to all Group Enrollees with ESRD, regardless of whether the Group Enrollees use Participating Dialysis Centers or Non-Participating Dialysis Centers, or whether the Group Enrollees use any particular provider, supplier, or practitioner for any other items or services. The Proposed Arrangement therefore does not raise concerns regarding inappropriate patient steering.

Fourth, the Requestor certified that it would not pressure, require, or otherwise unduly influence or coerce Group Enrollees with ESRD to enroll in Medicare Part B; rather, it would simply offer to pay the Medicare Part B premiums for all Group Enrollees with ESRD who qualify for, and who wish to enroll in, Medicare Part B. Group Enrollees with ESRD who choose not to enroll in Medicare Part B would retain all of their current benefits. Thus, Group Enrollees with ESRD could evaluate whether they would be better served, financially and otherwise, by enrolling in Medicare Part B or by preserving the status quo, and choose the more beneficial option.

Finally, for the reasons set forth in our analysis of the CMP, above, the Proposed Arrangement is unlikely to induce a Group Enrollee with ESRD to select a particular dialysis services provider. Moreover, the Requestor certified that it would not encourage Group Enrollees with ESRD either to continue to use or to switch to Non-Participating Dialysis Centers.

This opinion is limited to the narrow question of whether the Requestor's payment of Medicare Part B premium subsidies under the Proposed Arrangement implicates the CMP or the anti-kickback statute. We note that the Proposed Modified Benefit Design could also create an incentive for the Requestor to seek to lower the reimbursement rates for Participating Dialysis Centers. Any potential changes the Requestor might make to the Participating Dialysis Centers' PPAs, including any potential changes with respect to reimbursement, are not part of the Proposed Arrangement and would be beyond the OIG's advisory opinion jurisdiction. We express no opinion as to whether

the Proposed Modified Benefit Design would comply with State network adequacy regulations or any other Federal or state law or regulation.

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); the Medicare secondary payer provisions, section 1862(b) of the Act; and the regulations at 42 C.F.R. 411.102(a) regarding group health plans and individuals with ESRD.

- 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 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 [name redacted] 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