



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: August 9, 2013

Posted: August 16, 2013

[Name and address redacted]

Re: OIG Advisory Opinion No. 13-10

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding an entity's proposal to contract with hospitals to provide services to patients with certain diagnoses following hospital discharge with the goal of reducing preventable hospital readmissions (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. The Parties

[Name redacted] (the “Vendor”) is a wholly owned subsidiary of [name redacted] (the “Parent Company”), a major pharmaceutical manufacturer. The Vendor’s mission is to develop technology platforms and services that will better coordinate care, help patients adhere to their hospital discharge plans, and avoid preventable hospital readmissions. The Vendor certified that it does not manufacture, market, or distribute any pharmaceutical products. Although the Vendor shares certain overhead functions with the Parent Company, the Vendor certified that it has its own sales force, pricing strategy and approval committee, and marketing team. The Vendor’s sales representatives would not be compensated based on whether a client purchases the Parent Company’s products, and the Parent Company’s sales representatives would not be compensated based on whether a client purchases the Vendor’s services.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Vendor would sell hospitals a package of services designed to help them avoid the payment reductions associated with excess hospital

readmissions as set forth in the Hospital Readmissions Reduction Program (“the HRRP”).¹ Initially, the services offered through the Proposed Arrangement would be available to patients who were hospitalized with one of the conditions on which HRRP readmissions calculations are based, which currently are acute myocardial infarction, congestive heart failure, and pneumonia. When the HRRP expands to include additional conditions, the Vendor intends to expand the Proposed Arrangement accordingly. In addition, the Vendor also may expand its services to patients with conditions not included in HRRP readmissions calculations, depending on customer feedback. The Vendor certified that any such expansion would be subject to the same terms and conditions applicable to the initial program.

The Vendor would market and offer the Proposed Arrangement to hospitals either directly or through group purchasing organizations (“GPOs”) authorized to act as purchasing agents for hospitals.^{2,3} The agreements would be set out in writing, signed by both the Vendor and the hospital, and have a term of not less than one year. The agreements would specify and cover all of the services that the Vendor would provide to the hospital for the term of the agreement and would set forth the method for calculating all fees associated with the Proposed Arrangement. The Vendor would offer customers a “menu” of possible services, each of which is described in greater detail below. Contracting hospitals would be able to select and purchase services, on a patient-by-patient basis, that they expect would help reduce their preventable readmissions rates.

¹ The HRRP was established in section 3025 of the Patient Protection and Affordable Care Act (P.L. 111–148, 124 Stat. 119), as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111–152, 124 Stat. 1029) (collectively, the “ACA”).

² The Vendor may also market the Proposed Arrangement to patient-centered medical homes and managed care organizations, including Medicare and Medicaid managed care organizations. The Vendor certified that it would implement safeguards to prevent both a hospital and a managed care organization from paying for the services for the same patient.

³ The Vendor certified that any arrangements with GPOs would comply with the GPO safe harbor at 42 C.F.R. § 1001.952(j). We have not been asked about, and we express no opinion regarding, the Vendor’s arrangements with GPOs.

The Vendor certified that the standard fees, also described more fully below, would be fair market value.⁴ To the extent that the Vendor provides discounts to customers, the Vendor certified that any such discounts would be structured consistently with the discount exception to the anti-kickback statute and the discount safe harbor, and that the price for the services would still fall within the range of fair market value.

The Proposed Arrangement would include a number of services described herein (the “Services”). The Vendor expects that a nurse or other individual employed by a participating hospital, typically a discharge nurse (the “Discharge Nurse”), would identify a hospitalized patient who meets the eligibility criteria and explain the Services to the patient.⁵ If a patient elects to receive the Services (becoming a “Participating Patient”), the Discharge Nurse would initiate the transfer of the Participating Patient’s discharge plan⁶ into the software platform associated with the Proposed Arrangement. The Participating Patient’s primary care provider would receive a copy of the discharge plan. While the Participating Patient is receiving the Services, an electronic personal health record (the “Limited Electronic Health Record”)⁷ would be shared with members of the extended care team designated by the Participating Patient (e.g., the Participating Patient’s family caregivers, physician(s), and hospital care team).⁸

⁴ We are not authorized to opine on whether fair market value shall be, or was paid or received for any goods, services, or property. See section 1128D(b)(3) of the Act. We therefore rely on the Vendor’s certification that the fees will represent fair market value in an arm’s-length transaction.

⁵ The Vendor’s agreements with hospitals would contain a representation and warranty that the Discharge Nurse may not be compensated based on the number of patients enrolled in the Proposed Arrangement.

⁶ The Proposed Arrangement would not affect the discharge plan and discharge planning process, which would be created and performed independently of the Vendor.

⁷ The Limited Electronic Health Record would include only the discharge plan and information necessary to follow the instructions in the discharge plan, as later supplemented by the Participating Patient or the Participating Patient’s care team while the Participating Patient is receiving the Services.

⁸ As a condition of receiving the Services, Participating Patients would be required to sign a written authorization for the disclosure and use of their personal health information contained in the Limited Electronic Health Record for purposes of the Proposed Arrangement. The authorization would permit disclosure of personal health information to, among others, the Vendor (solely for purposes of fulfilling adverse event reporting

Participating Patients would have access, for a 12-hour period each day, to an individual who would help them understand and follow their discharge plans (“Patient Liaison”). For the 12-hour period during which Patient Liaisons were not available, Participating Patients would be automatically transferred to a 24-hour nurse hotline, described below. The Patient Liaison would contact each Participating Patient within 48 hours of discharge to make sure that he or she understands and will follow the discharge plan. Thereafter, the Patient Liaison would contact Participating Patients daily (or at the intervals selected by the contracting hospital) to administer questionnaires about the Participating Patient’s health and compliance with the discharge plan.⁹ Participating Patients also could answer the questionnaires via the internet or through a telephone interactive voice response (“IVR”) system.¹⁰ The Patient Liaison (or an internet or IVR system) would ask Participating Patients about medication compliance, remind them about refills, and add any newly prescribed medication into the Participating Patient’s Limited Electronic Health Record. All of these steps would be taken regardless of what company manufactures the Participating Patient’s medication, whether the medication is brand or generic, or where the prescription is filled. The Patient Liaisons or the Proposed Arrangement’s website or IVR system also could: assist Participating Patients with various tasks, such as scheduling follow-up appointments, reminding them about scheduled appointments, or helping them obtain transportation (at the Participating Patients’ own cost); provide Participating Patients with unbranded educational materials intended for general audiences; and provide updates to Participating Patients’ caregivers and primary care providers. The software used in the

obligations, handling product quality complaints, and providing technology support) and the entities contracting with the Vendor or otherwise involved in managing the data and technology services for purposes of the Proposed Arrangement. The Vendor certified that the authorization would comply with all applicable Federal and state data privacy laws.

⁹ The Vendor certified that the questions would be tailored to the Participating Patient’s primary diagnosis and would be consistent with evidence-based, clinical treatment guidelines for that diagnosis.

¹⁰ The Vendor certified that the hospital would assign the Participating Patient’s questionnaire communication mechanism (i.e., a call from a Patient Liaison, the internet, or via IVR system) based on its independent, professional assessment of the Participating Patient. However, the hospital may also give Participating Patients the option to modify their communication mechanism based on their individual preferences. If a Participating Patient responds to the questionnaires via internet or IVR, the Patient Liaison would not call the Participating Patient after the initial call in the first 48 hours unless the system flags the Participating Patient’s internet/IVR questionnaire responses for further follow-up by the Patient Liaison.

Proposed Arrangement also may generate reports to help hospitals monitor the use of the Services. The reports would include information on Participating Patients' medication adherence, post-discharge physician appointment completion, readmission rates, demographics, readmitting hospitals, and secondary diagnoses.

Patient Liaisons would not necessarily have a medical background. Therefore, a Patient Liaison would transfer a Participating Patient to a 24-hour nurse hotline under various circumstances, such as if the Participating Patient had any questions about the discharge plan or other medical questions, if any new prescription information entered was flagged by the automated computer system as having an interaction with the Participating Patient's current medications, or if responses to the questionnaires prompt him or her to do so.¹¹ The nurse hotline would be staffed by licensed nurses who are employed either by the hospitals that enter into the Proposed Arrangement or by an independent third party that is under contract with the Vendor. The Vendor certified that nurses employed by its independent third party contractor would not promote the Parent Company's products or be compensated on the basis of sales of such products. Moreover, regardless of a Participating Patient's question or symptom, the nurses would not refer him or her to any provider or supplier other than the Participating Patient's established primary care practitioner, specialist(s), or admitting hospital, as recorded in the Proposed Arrangement's software. Participating Patients would be free to designate any primary care practitioners, specialists, or admitting hospitals as their established providers.

The Patient Liaisons would be employed by a customer service subsidiary of the Parent Company. The Vendor certified that the Patient Liaisons would not promote any drug products nor would their compensation be based in whole or in part on whether the hospital purchases any of the Parent Company's products. The Patient Liaisons would not have any marketing responsibilities.¹² However, they would develop summary reports of their customer services activities (e.g., the number of calls offered, the number of calls answered, the average speed to answer, and the length of each call), and those reports would be shared with the Vendor and individuals responsible for marketing the Proposed Arrangement. The

¹¹ Patient Liaisons would receive a notification if a Participating Patient responding via the internet or IVR system responds in a way that would trigger a transfer to the nurse hotline. The Patient Liaison would call the Participating Patient to confirm the response, and then transfer him or her to the hotline if necessary.

¹² The Vendor may decide to offer a more limited version of the Services for Participating Patients to purchase after the Participating Patient's hospital ceases providing the Services. If so, Patient Liaisons would describe this option to Participating Patients. We express no opinion about this potential future marketing activity.

Vendor certified, however, that patient data (de-identified or otherwise) collected under the Proposed Arrangement would not be used to market the Parent Company's products. The Vendor certified that neither it nor the Parent Company would allow individuals with access to such patient information to share that information with any individuals with responsibility for marketing the Parent Company's products.

The Vendor indicated that it may offer additional services in the future. For example, the Vendor may offer enhanced versions of the Services offered in the basic program (e.g., by adding more metrics to the reports that the hospitals would receive, by offering supplemental technology resources if a hospital requires a customized data connection to implement the Proposed Arrangement, or by offering medication reconciliation data services). The Vendor certified that any such additional services would be subject to all the same safeguards as the Services described herein.

The Vendor disclosed that it is also conducting beta testing of the Proposed Arrangement at a small number of hospitals. The fees charged during the beta testing are different from the fees that would be charged for the Services under the Proposed Arrangement, and the Vendor pays the hospitals for certain services provided during this testing phase (e.g., providing structured feedback). The Vendor has not asked, and we express no opinion about, the services and fees provided during the beta testing phase.

C. Fees

The Proposed Arrangement would include three different fees. First, each participating hospital or hospital system would pay a flat fee (the "Initial Fee") for implementation services.¹³ These services could include electronic health record data integration to coordinate the electronic transfer of the Participating Patients' discharge plan into the software platform associated with the Proposed Arrangement, any needed hardware, consultation and co-creation of new hospital processes for eligible patient identification and enrollment, and initial training of hospital staff.

The second fee the Vendor would charge would be a per-patient fee ("Annual Fee") that would compensate the Vendor for technology and personnel costs, system maintenance and software upgrades, and user support services. This fee would include several components, including the total of the Services received by each Participating Patient (i.e., the items that the hospital chose from the menu of Services for that Participating Patient) and other

¹³ A portion of the Initial Fee could be offset in various ways, such as if the hospital meets certain resource requirements (e.g., timely access to the electronic health records network, hospital information technology human resources, and a satisfactory on-site work space) or implements the Proposed Arrangement at multiple affiliated hospitals.

factors, such as whether the hospital uses its own nurses for the nurse hotline. The Vendor certified that the fee for each component would be set in advance and would be fair market value. A portion of this fee would be paid up-front based on a percentage of the projected patient enrollment (which may include a breakdown of estimated enrollment at different levels of available Services) in the program. On an annual basis, the Vendor would reconcile the Annual Fee with the hospital's actual enrollment volume and actual menu selections per Participating Patient, and the hospital would make an additional payment to the extent that the actual use exceeded the amount already paid. However, the up-front portion of the fee paid would not be reduced if the enrollment volume and selection of Services was lower than projected. The Vendor would offer an alternative structure for the Annual Fee under which a participating hospital would not have to pay the Annual Fee for any Participating Patient who is readmitted to a hospital within a specified number of days after being discharged from the hospital, provided the Participating Patient had not complied with his or her discharge plan.

For hospitals that request additional services, examples of which are described above, the Vendor would charge separate fees ("Additional Fees"). These Additional Fees would be based on the hourly rate of the employees performing the extra services, plus any additional expenses incurred by the Vendor, plus a reasonable profit margin.

The standard rates for the Initial Fees and Annual Fees would be fair market value, as determined by the Vendor's market research and cost analyses and confirmed by an independent third party assessment. The Vendor also certified that the Additional Fees would be consistent with fair market value based on the Vendor's own analysis; because of the customized nature of the services covered by these fees, the Vendor stated that they do not lend themselves to a "list" price. The availability or price of the Proposed Arrangement would not be tied to customer formulary decisions or drug purchasing or prescribing patterns. The Vendor's customers would be informed of this policy in agreements 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 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 Vendor, a wholly owned subsidiary of a pharmaceutical company, would provide a number of services to hospitals, and those hospitals would offer the patient-centered services to certain patients. We analyze this Proposed Arrangement under both the anti-kickback statute and section 1128A(a)(5) of the Act (the “CMP”) below.

1. Anti-kickback Statute

The anti-kickback statute prohibits knowingly and willfully offering or giving remuneration to induce or reward referrals of items or services payable by a Federal health care program. Under the facts of the Proposed Arrangement, both parties are potential referral sources for each other. The Vendor is a subsidiary of a pharmaceutical company and could provide the

Services at below fair market value either to obtain data to market the Parent Company's products or to induce a hospital to purchase or prescribe the Parent Company's drugs. A hospital could also be a referral recipient under the Proposed Arrangement; it could pay above fair market value for the Services to induce the Vendor's employees or contractors to refer patients to the hospital.

Under the particular facts and circumstances presented here, we conclude that the Proposed Arrangement poses a low risk of fraud and abuse under the anti-kickback statute.

First, the Proposed Arrangement is unlikely to lead to increased costs or overutilization of Federally reimbursable services. The Services themselves currently are not separately reimbursable by Federal health care programs. Although the Services could increase utilization (e.g., by reminding Participating Patients to take their medications or attend necessary follow-up visits), such an increase likely would result in appropriate utilization by helping the Participating Patient comply with the hospital's discharge plan. The Services could potentially save the Federal health care programs money if the Proposed Arrangement is successful in furthering its goal of decreasing excess hospital readmissions.

Second, the Proposed Arrangement is unlikely to interfere with clinical decision-making. Hospitals would offer the Services only to patients who already were hospitalized with certain conditions. Participating Patients would not begin to receive the Services until after they have been discharged from the hospital. The Services are designed to promote compliance with the discharge plan as designed by the Participating Patient's care team, including, but not limited to, promoting compliance with all prescribed therapies, regardless of which drugs are prescribed to the Participating Patient or which company makes those drugs.

Third, the Vendor certified that it would implement a number of safeguards to prevent the Proposed Arrangement from being used to increase drug sales by the Parent Company.¹⁴ The Services would be designed to promote adherence to all medication therapies, regardless of what company manufactures or markets the drugs. Neither the availability of, nor the fees associated with, the Proposed Arrangement would be tied to formulary decisions or drug purchasing or prescribing patterns. The Vendor and the Parent Company have separate sales forces, and neither entity's sales representatives would be compensated based on whether a client purchases the other entity's products. Neither the Patient Liaisons

¹⁴ We rely on the Vendor's certifications regarding these safeguards and that such safeguards will, in fact, prevent the Proposed Arrangement from being used to increase the Parent Company's drug sales. If any of these certifications proves to be false, this opinion is without force and effect.

nor the nurses staffing the nurse hotline would promote the Parent Company's products or be compensated on the basis of any sales of such products. Moreover, the Vendor certified that the fees charged under the Proposed Arrangement would be consistent with fair market value in an arm's-length transaction and, with the "menu" structure, the hospitals would be able to purchase only the Services that they need.¹⁵ As we noted above, we are not authorized to opine on fair market value and must rely on the Vendor's certification. We are satisfied that these safeguards sufficiently reduce the risk of the Proposed Arrangement inappropriately increasing sales of the Parent Company's products.

Fourth, the Proposed Arrangement is unlikely to result in inappropriate patient steering. Only patients who have already been admitted to the hospital with one of certain specified conditions as a primary diagnosis would be eligible to receive the Services. The two categories of individuals who would interact with Participating Patients—the Patient Liaisons and the nurses staffing the hotline—would be prohibited from referring Participating Patients to any provider, practitioner, or supplier that the Participating Patient had not designated upon agreeing to receive the Services. Thus, the risk of patient steering appears to be minimal.

For the combination of the foregoing reasons, we find that the Proposed Arrangement presents a sufficiently low risk of fraud and abuse under the anti-kickback statute.

2. The CMP

The CMP prohibits offering or transferring remuneration to Medicare or Medicaid beneficiaries that such person knows or should know is likely to influence a beneficiary to order or receive a Federally payable item or service from a particular provider, practitioner, or supplier. Here, hospitals offer the Services to patients, but the Vendor would be compensated for making the Services available to, and directly interacting with, Participating Patients. Participating Patients unquestionably would receive a valuable service without cost under the Proposed Arrangement. However, under the particular facts present here, we do not believe that the Services would be likely to influence Participating Patients to order or receive a Federally payable item or service from a particular provider, practitioner, or supplier.

¹⁵ We recognize that the Annual Fees are calculated on a per-patient basis. Per-patient or similar variable compensation structures often are problematic under the anti-kickback statute, because they relate to the volume or value of business potentially generated between parties. Here, however, the hospitals would both identify the patients who are eligible to receive the Services and pay the per-patient fee to the Vendor. Thus, the more patients the hospital identifies, the more the hospital *pays* for the Services. Under these circumstances, it seems unlikely that the per-patient fees would serve as remuneration to induce referrals.

First, upon agreeing to receive the Services, a Participating Patient would designate the providers, practitioners, and suppliers he or she wishes to include in the software platform associated with the Proposed Arrangement. The Patient Liaisons and the nurses staffing the nurse hotline would not be permitted to refer the Participating Patient to any provider, practitioner, or supplier not included on that list. Although the offering hospital likely would be included on the list, the Participating Patients would have already selected that hospital as their provider for certain services; it is unlikely that the existence of the Proposed Arrangement would significantly influence a Participating Patient to select the hospital for future services.

Second, the Proposed Arrangement would not involve providing any rewards or incentives to Participating Patients that would be likely to influence their selection of a provider, practitioner or supplier; the Proposed Arrangement primarily makes available a person to remind Participating Patients to follow a discharge plan that was established independently of the Proposed Arrangement and assist Participating Patients with administrative tasks related to those instructions.

To effectively carry out the goals of the HRRP, hospitals may need to become more engaged in patients' care during the post-discharge period. Under the particular facts and circumstances present here, the Proposed Arrangement appears to be a low risk method of guiding Participating Patients during the post-discharge period, without influencing or limiting the Participating Patients' choice of provider, practitioner, or supplier.

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 the [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 [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