[*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 29, 2011

Posted: September 6, 2011

[Name and address redacted]

Re: OIG Advisory Opinion No. 11-12

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a health system's proposal to enter into arrangements to provide neuro emergency clinical protocols and immediate consultations with stroke neurologists via telemedicine technology to certain community hospitals (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (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, while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to

induce or reward referrals of Federal health care program business were present, the Office of Inspector General ("OIG") would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] (the "Requestor") is an operating division of the not-for-profit corporation [name redacted]. Through its flagship hospital, the Requestor provides nationally-ranked neuroscience care. The Requestor states that part of its mission is to spread the availability of its quality and excellence throughout the region in which it is located, including by developing programs that foster enhanced access to high-quality tertiary/quaternary neuroscience services.

Recent statistics indicate that stroke is the third leading cause of death in the nation and a leading cause of serious, long-term disability.[1] The Requestor states that, for legal reasons, community hospitals frequently transfer suspected stroke patients to comprehensive stroke centers that have the medical resources to treat acute stroke and other neuro emergencies that may present with stroke-like symptoms. The Requestor also states that, although acute stroke is a treatable illness, time is of the essence in its treatment and, therefore, treatment is most effective when commenced in the emergency department. Hospitals with the proper support of a comprehensive stroke center can safely and effectively treat simple stroke cases, rather than transfer them to a comprehensive stroke center, thus allowing treatment to begin at the time that it is most effective.

Comprehensive stroke centers frequently offer local community hospital emergency departments access to stroke neurologists 24 hours a day, seven days a week, 365 days a year ("24/7/365"); however, according to the Requestor, consultations between emergency physicians and stroke neurologists typically take place over the telephone, thus limiting the quality of information the parties can exchange. The Requestor further

[1] See, e.g., Centers for Disease Control and Prevention, "Stroke Facts," available at http://www.cdc.gov/stroke/facts.htm.

states that consultation arrangements between comprehensive stroke centers and local community hospitals have, historically, been informal and ad hoc.

Under the Proposed Arrangement, the Requestor would provide, at its expense, the following items and services to certain community hospitals in the Requestor's service area (each, a "Participating Hospital"): (i) neuro emergency telemedicine technology; (ii) neuro emergency clinical consultations; (iii) acceptance of neuro emergency transfers; and (iv) neuro emergency clinical protocols, training, and medical education (collectively, the "Program"). In addition, the Requestor and the Participating Hospitals would have the opportunity to use each other's trademarks and service marks for certain marketing activities in connection with the Program.

The Program initially would be offered to community hospitals in the Requestor's service area with which the Requestor has pre-existing, significant contractual relationships[2] ("Affiliated Hospitals"). The Requestor has certified that neither the continued transfer of stroke patients to the Requestor nor the value or volume of any other business generated between the parties would be a condition of participation. The Requestor further certified that, to the extent that it elects to make participation in the Program available to community hospitals with which it does not have pre-existing, significant contractual relationships ("Non-Affiliated Hospitals"), the decision as to which Non-Affiliated Hospitals to offer the Program would not be based on the volume or value of the Non-Affiliated Hospital's previous referrals, or on any arrangement or understanding regarding anticipated referrals. Rather, Program participation would be extended to Non-Affiliated Hospitals based on rational access-to-care considerations, including the Non-Affiliated Hospital's location, the location of other stroke programs, the local population density, and the Requestor's resources for the Program.

The Requestor has certified that the Program aims to reduce the mortality and morbidity rates of stroke in the Requestor's metropolitan area and lower the costs associated with transfers of stroke cases that, with the Program's support, could be managed at the Participating Hospitals. The Requestor certified that it receives a significant volume of transfers of stroke patients who could effectively be treated in their local community hospitals with the appropriate clinical support. The Requestor expects that the Program would reduce the volume of these transfers and that this reduction would, in turn, free up resources for patients who require the level of tertiary care that the Requestor's hospital can provide.

The Requestor would enter into a written agreement with each Participating Hospital that sets forth all of the services to be provided by each party under the Program. In recognition of the Requestor's investment of time and capital in the Program, the

[2] According to the Requestor, these contractual relationships typically involve some sort of clinical affiliation, such as participation in the Requestor's cancer network.

Participating Hospitals must agree not to participate in any other neuro emergency telemedicine service without the Requestor's prior approval for the length of the agreement, which the Requestor anticipates would be two years. The Requestor has certified that this exclusivity requirement would not: (i) restrict a Participating Hospital's emergency or attending physician from consulting by phone or in-person with any stroke specialist of his or her choice; (ii) require either party or any physician on its medical staff to refer patients to the other party; or (iii) restrict the freedom of a patient or the patient's physician to request a transfer to a stroke center other than the Requestor's stroke center.

We provide a brief description of each of the Program's components, below.

Neuro Emergency Telemedicine

The Requestor's contracted telemedicine service provider would, at the Requestor's expense, install neuro emergency telemedicine technology, including both hardware and software, in the Participating Hospitals' emergency departments. The telemedicine service provider would provide maintenance, upgrades, technical training, and support services pursuant to a contract between it and the Requestor. Central to the telemedicine technology is a web-enabled stroke treatment consultation and decision support system with integrated audio-visual capabilities (the "Tele-Stroke Application") that would enable the Requestor's neurologists, who have extensive training and experience in the treatment of stroke, to consult, in real time, with the Participating Hospitals' emergency physicians.

Each Participating Hospital would be required to, among other things: (i) enter into, and comply with, an end user license agreement with the telemedicine service provider; (ii) at its own expense, install and maintain the communication links and connectivity necessary for the telemedicine technology to link with the Requestor; and (iii) at its own expense, install and maintain at least one computed tomography ("CT") scanner capable of transmitting CT scan images to a remote server, thereby permitting the Requestor's neurologists to view the images remotely. The Requestor has certified that neither it nor any Participating Hospital would bill any patient or third party payor for the cost of the telemedicine technology.

Neuro Emergency Clinical Consultations

The Requestor would, at its expense, furnish the Participating Hospitals' emergency physicians with 24/7/365 access to the Requestor's stroke expertise, via both telephone and the Tele-Stroke Application. If medically necessary, one of the Requestor's neurologists would examine the patient in real-time using the Tele-Stroke Application, view the CT scans performed in the Participating Hospital's emergency department through remote access, and make recommendations based on his or her clinical

assessment. The Participating Hospitals would be required to, among other things, facilitate the medical staff credentialing of the Requestor's neurologists and their appointments as consulting physicians on an expedited basis. The Requestor states that although few, if any, of the consultations would be billable to Medicare, to the extent the consultations are covered and payable by third party payors, it would bill and collect for them.[3]

Acceptance of Neuro Emergency Transfers

The Requestor would, at its expense, ensure that neurosurgeons and neuro intensivists are on call and available to accept transfers of acute stroke patients from the Participating Hospitals. Each Participating Hospital must represent and warrant to the Requestor that: (i) it would at all times respect the independence of its emergency physicians' clinical judgment and its patients' freedom of choice; (ii) no emergency physician's compensation would take into account the volume or value of the physician's referrals to the Requestor; and (iii) no emergency physician would receive additional remuneration as a result of the Program.

Neuro Emergency Clinical Protocols, Training, and Medical Education

The Requestor would, at its expense, furnish neuro emergency clinical protocols to the Participating Hospitals and offer access to neuro emergency training and medical education programs to the Participating Hospitals' emergency department staffs. The programs would include: (i) initial training sessions designed to ensure that the Participating Hospitals' staffs are well-versed in the use of the Tele-Stroke Application and stroke assessment protocols, and (ii) opportunities for the Participating Hospitals' staffs to participate in Requestor-run events intended to further the physicians' education, such as the ability to participate in grand rounds and special stroke-related events.[4] The Requestor has certified that the training and medical education programs would take place either at the Participating Hospital or at the Requestor's hospital, as appropriate.

[3] The Requestor has certified that: (i) this policy would not represent a change from its current billing practices, and (ii) it does not anticipate that the use of the Tele-Stroke Application would allow it to bill for consultations for which it otherwise could not have billed if performed using the telephone.

[4] The Requestor certified that the medical education programs likely would be informal and collaborative in nature and consistent with the ordinary course of the Requestor's internal education and training programs, and would not be comparable to the type of continuing medical education that is available for commercial purchase.

Marketing and Advertising

Subject to the Participating Hospital's prior approval of each specific use of its name and marks, each Participating Hospital would grant the Requestor a limited, non-exclusive, royalty-free license to use the Participating Hospital's trademarks and service marks for purposes of marketing the Program. Conversely, subject to the Requestor's prior approval of each specific use of its name and marks, the Requestor would grant the Participating Hospital a limited, non-exclusive, royalty-free license to use [trademark redacted] and associated trademarks and service marks for purposes of marketing the Participating Hospital's stroke service line. The Requestor has certified that neither party would be required to engage in marketing activities under the Proposed Arrangement and that each party would be responsible for the cost of its own marketing, including any marketing involving the use of the other party's name or marks.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by 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. 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.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The

safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Proposed Arrangement. Among the conditions of the personal services and management contracts safe harbor is that agreements for services to be provided on a periodic, sporadic, or part-time basis must specify exactly the schedule of such intervals, their precise length, and the exact charge for such intervals. See 42 C.F.R. § 1001.952(d)(3).

B. Analysis

The Requestor and the Participating Hospitals are potential sources of referrals of Federal health care program business to one another. As such, the exchange of anything of value between them potentially implicates the anti-kickback statute.

As a threshold matter, safe harbor protection is not available for the Proposed Arrangement. Under the safe harbor for personal services and management contracts, agreements for services to be provided on a periodic or sporadic basis must specify the schedule of such intervals, their precise length, and the exact charge for such intervals. Because the Participating Hospitals' physicians would use the Tele-Stroke Application to consult with the Requestor's neurologists—and, if medically necessary, to facilitate the Requestor's neurologists' examination of the patient—on an unscheduled, as-needed basis, the Proposed Arrangement cannot fit squarely within the terms of the safe harbor. We therefore must analyze the Proposed Arrangement for compliance with the anti-kickback statute by taking into account the totality of the facts and circumstances.

For the reasons set forth below, we conclude that the facts and circumstances of the Proposed Arrangement, in combination, adequately reduce the risk that the remuneration provided under the Proposed Arrangement could be an improper payment for referrals of Federal health care program business.

First, the Requestor would be unlikely to generate appreciable referrals through the Proposed Arrangement. Neither the Participating Hospitals nor their physicians would be required or encouraged to refer patients to the Requestor's hospital as a condition of Program participation, and no emergency physician would receive additional compensation under the Program. Further, the Requestor has stated that an express objective of the Program is to reduce the number of transfers of stroke patients to the Requestor's hospital in circumstances where those patients may be managed, with the appropriate clinical support, by a Participating Hospital. Although the Participating Hospitals must commit to a period of exclusivity under the Proposed Arrangement, the

exclusivity requirement would prohibit the Participating Hospitals only from participating in another neuro emergency telemedicine service without the Requestor's prior approval; the exclusivity provision would not prohibit the Participating Hospitals' emergency physicians from consulting with other neurologists in-person or by telephone. Further, the Participating Hospitals' physicians would remain free at all times to refer their patients to a facility other than the Requestor's hospital.

Second, under the Proposed Arrangement, Program participation initially would be offered to Affiliated Hospitals—i.e., hospitals with which the Requestor typically has some sort of clinical affiliation. If resources permit, Program participation would be offered to Non-Affiliated hospitals based on rational access-to-care considerations. With respect to both Affiliated Hospitals and Non-Affiliated hospitals, neither the volume or value of a hospital's previous or anticipated referrals, nor the volume or value of any other business generated between the parties, would be a condition of Program participation.

Third, while both the Participating Hospitals and the Requestor might benefit from the Proposed Arrangement, the primary beneficiaries would be the stroke patients who, with the Program's support, could be treated at the Participating Hospitals' emergency departments, when treatment is most effective.[5] Further, because the Program likely would reduce the volume of transfers of stroke patients to the Requestor's hospital, patients who need the level of tertiary care that the Requestor's hospital can provide, but who might not otherwise have been able to receive it due to capacity issues, might also benefit.

Fourth, although the Proposed Arrangement would afford the Requestor and the Participating Hospitals the opportunity to engage in marketing activities using each other's marks, neither the Requestor nor any Participating Hospital would be required to engage in any marketing activities, and each party would be responsible for the costs associated with its own marketing activities.

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[5] The Participating Hospitals' physicians might also benefit from the Proposed Arrangement, as they would have the opportunity to enhance their professional skills by attending medical education programs offered as part of the Program. However, the medical education programs would not be comparable to the type of continuing medical education that is available for commercial purchase, and thus would differ substantially from those that pose a greater risk of fraud or abuse, such as continuing medical education services sponsored or funded by pharmaceutical manufacturers. See, e.g., "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," 68 Fed. Reg. 23,731 (May 5, 2003), available at http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf.

Finally, the Proposed Arrangement is unlikely to result in increased costs to the Federal health care programs. The Requestor certified that few—if any—of the consultations it would provide under the Program would be billable to Medicare. Further, because the Program is designed to reduce the volume of transfers of stroke patients to the Requestor's hospital, the costs associated with these transfers, such as ambulance services, would correspondingly decrease. The timely treatment of stroke patients would also likely decrease the incidence of stroke-related disabilities, which, in turn, would likely decrease the costs associated with treating and supporting such patients. The Federal health care programs would be likely to benefit from these decreased costs.

In short, as structured, the Proposed Arrangement appears to contain sufficient safeguards to reduce the risk that it would result in improper payments for referrals of Federal health care program business for the Requestor. Moreover, the Proposed Arrangement promotes the obvious public benefit of promoting timely access to specialty care for acute stroke patients. In light of the totality of the facts and circumstances presented, we would not subject the Requestor to sanctions under the anti-kickback statute in connection with the Proposed Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, while 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 in any matter involving an entity or individual that is not a requestor of this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 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 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General