[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requester*.]

Issued: December 28, 1999

Posted: January 6, 2000

[Name and address redacted]

Re: OIG Advisory Opinion No. 99-14

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion about a rural telemedicine network arrangement implemented and operated pursuant to Federal grants from the Office of Rural Health Policy ("ORHP") and the Office for the Advancement of Telehealth ("OAT"), divisions of the Health Resources Services Administration ("HRSA"). Specifically, you have inquired whether the use of Federal grant funds and the continued operation of the telemedicine network after the expiration of the grant period would, in the circumstances presented, constitute grounds for the imposition of sanctions for violations of the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), pursuant to sections 1128(b)(7) and 1128A(a)(7) of the Act.

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 information provided, we conclude that the Arrangement (as defined in the next sentence) could potentially involve prohibited remuneration under section 1128B(b) of the Act, if the requisite intent to induce referrals were present; however, the Office of Inspector General ("OIG") will not impose sanctions on Health System A ("Health System A") for violations of the anti-kickback statute arising under sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Arrangement (limited as set forth in the next sentence), as described and certified in the request letter and supplemental submissions. For purposes of this advisory opinion, the "Arrangement" means, collectively, Health System A's (i) use of Federal grant funds under the terms of the ORHP/OAT grants; (ii) continued provision of telemedicine consultations within the Telemedicine Network ("Telemedicine Network") after the end of the grant period; (iii) continued payment of transmission line charges related to the Telemedicine Network (whether by Health System A or third party sources arranged for by Health System A) after the end of the grant period; (iv) continued payments after the end of the grant period to an unrelated third-party vendor to maintain the existing telemedicine equipment owned by Health System A until January 2003; (v) lease of telemedicine equipment to members of the Telemedicine Network pursuant to leases that satisfy the equipment rental safe

harbor at 42 C.F.R. º 1001.952(d) after the end of the grant period; and (vi) participation in the administration of the Telemedicine Network for telemedicine purposes after the end of the grant period.[(1)]

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

I. BACKGROUND

A. The Rural Telemedicine Grant Program

We begin with a discussion of the relevant Federal telemedicine grant programs. For purposes of this advisory opinion, the two grant programs described below will be collectively referred to as the "Telemedicine Grant Program" or "TGP".

Congress established the Rural Telemedicine Grant Program through the Department of Health and Human Services Appropriations Act of FY 1994 (Pub. L. 103-112) to demonstrate and collect information on the feasibility, cost, appropriateness, and acceptability (to practitioners and patients) of telemedicine consultations for improving access to health care services for rural residents and for reducing the isolation of rural practitioners. The program, administered by ORHP (later OAT[(2)]), was designed to demonstrate how telemedicine could be used as an effective tool in the development of integrated systems of health care for rural residents. See 1994 TGP Program Guide at 1.

For purposes of the TGP, ORHP defined telemedicine as the use of telecommunications for medical diagnosis and patient care, including patient counseling and clinical training of residents and health professions students when such training is a by-product of direct patient care. See Id. at 1. Under the 1994 grant program, telemedicine consultations could be performed with or without the patient present, as appropriate. See id. at 2.

The 1994 grant program required recipients to participate in a telemedicine network composed of (i) a "hub" multi-speciality entity capable of providing 24-hour a day specialty consultations for all specialty services offered through the network[(3)] and (ii) at least one small rural hospital (fewer than 100 beds) and one rural primary care practitioner office or clinic (the "spokes"). Other rural sites could also participate, including long-term care facilities, mental health clinics, school-based clinics, emergency services providers, home health providers, and health professions schools. See id. at 1-2.

To be eligible for grant purposes, a telemedicine network had to consist of a partnership (whether a consortium of independent entities or other more formal affiliation)[(4)] evidenced by:

- a resource contribution from each member (in cash or in kind);
- a specified role for each member;

- active participation of each member in the planning and implementation of the telemedicine project;

- a clearly articulated relationship evidenced by a signed and dated memorandum of agreement delineating the roles and resource contributions of each member; and

- a long-term commitment by each member to continue working together beyond the funding period of the grant program.

See id. Grant recipients had to provide teleconsultation services in a minimum of eight core areas: teleradiology, cardiology, dermatology, mental health and/or substance abuse, obstetrics and gynecology, orthopedics, subspecialities of pediatrics, and resuscitation of trauma patients. See id. at 3. TGP grants were typically awarded to the "hub" entities or to the network itself (if the network were a legal entity capable of receiving grant funds).

In 1996, Congress passed the Health Centers Consolidation Act of 1996 ("HCCA"), which established, *inter alia*, the Rural Health Outreach, Network Development, and Telemedicine Grant Program under section 330A of the Public Health Service Act (42 U.S.C. º 254c) and specifically authorized the Director of ORHP to award grants "to expand access to, coordinate, restrain the cost of, and improve the quality of essential health care services, including preventive and emergency services, through the development of integrated health care delivery systems or networks in rural areas and regions." 42 U.S.C. º 254c(b). Under HCCA, telemedicine grants could be used within specified limits to:

- demonstrate the use of telemedicine in facilitating the development of rural health care networks and improving the access to health care services for rural citizens;

- provide a baseline of information for a systematic evaluation of telemedicine systems serving rural areas;

- purchase or lease and install telemedicine equipment; and

- operate and evaluate the telemedicine system.

42 U.S.C. º 254c(e)(3)(A).

In 1997, the TGP grant application procedure and requirements were largely the same as in 1994, except that ORHP additionally required all applicants to document current referral patterns, including both referral patterns among network members and referral patterns that extended beyond network members. See 1997 TGP Program Guide. In addition, ORHP allowed grant funds to be used to make clinician incentive payments to consulting specialists of up to $60 per consultation, so long as there were no third-party payers, including Medicare and Medicaid, that *could* be billed for such consultations (regardless of whether they were in fact billed). See id. at 3. The 1997 grant required applicants to provide at least seven clinical telemedicine services, specifically including

the stabilization of patients in emergency situations and at least two consultative services provided by physician specialists. The grant recipients could select the other six services based on community need (e.g., services not available locally or services rural residents might forgo if they had to travel far or often to receive them). See id. at 18.

B. The Arrangement

The Arrangement is a telemedicine network organized by Health System A and ten outlying rural facilities and funded in part through two TGP grants.

Health System A is a [# redacted]-bed regional health care center located in City W, State X, serving over [# redacted] persons spread over [# redacted] square miles in [geographical designation redacted] State X and [geographical designation redacted] State Y. Health System A is a 501(c)(3) tax-exempt charitable institution consisting of the following subsidiaries: Health System A Hospital (a [# redacted]-bed general acute care hospital and U.S. Designated Regional Referral Center), Hospital B (an [# redacted]-bed psychiatric and chemical dependency facility), [names of subsidiaries redacted], and Health System A Hospital Foundation, a 501(c)(3) tax-exempt charitable institution whose mission is to support the health care services, research, and educational mission of Health System A. Health System A belongs to Network C, a national health care network. Health System A also participates in a physician-hospital organization with its medical staff and is developing a health maintenance organization to provide services in its service area.

In 1994, Health System A formed the Telemedicine Network[(5)] with the stated goal of using telemedicine to provide better access to health care services for rural citizens at remote locations without the inconvenience or risks normally associated with travel or delays in treatment. Telemedicine Network's service area includes approximately [# redacted] residents in an area of approximately [# redacted] square miles. Telemedicine Network currently consists of Health System A (the "hub") and [# redacted] outlying rural health care facilities (the "spokes"), including [# redacted] hospitals and [# redacted] rural health clinics.[(6)]

Each outlying "spoke" facility has a written telemedicine network provider agreement with Health System A. Under these agreements, Health System A agrees to provide the "spoke" facilities with technical communications capability, telemedicine equipment (which remains the property of Health System A), and technical assistance and training. In addition, Health System A agrees to coordinate the Telemedicine Network telemedicine program and assume responsibility for paying transmission line charges during the period it receives grant funds under the TGP. In turn, the "spokes" agree to provide space and a consultation room for the telemedicine equipment (including any remodeling necessary to accommodate the equipment), site facilitators, local data collection and documentation assistance, additional equipment such as video cassette recorders and video tapes, and security for the telemedicine equipment. The "spokes" also agree to promote the use of the Telemedicine Network for medical consultations to their medical staffs and to encourage and train their physicians in the implementation of the

telemedicine program.

In 1994 and again in 1997, Health System A Hospital Foundation applied for, and was awarded, TGP grants to support the Telemedicine Network in the amounts of $[x] and $[y], respectively.[(7)] Each grant had a three-year term. The grant funds were designated in part for the purchase of telemedicine equipment and its placement in the outlying "spoke" facilities and for payment of necessary line costs so that patients, physicians, and other health care professionals could receive professional consultations from physicians at Health System A's tertiary care facilities: Health System A Hospital and Hospital B.[(8)] The 1997 grant funds were further designated to pay fees to the physicians providing the consultations.

Health System A has certified that its use of the TGP grant funds has been, and will continue to be, consistent with the statutory and regulatory TGP grant guidelines and conditions, which include, without limitation, the following:

- Funds may be used to support the operating costs of the telemedicine system, including compensation for specialists and referring practitioners.

- No more than 40% of the total grant award may be used to purchase or lease telemedicine equipment. No grant funds may be used for the costs of purchasing and installing transmission equipment, such as laying cable or telephone lines, microwave towers, digital switching equipment, amplifiers, and the like. Grant funds may be used to pay transmission costs, such as the cost of satellite time or use of phone lines.

- Grant funds may not be used for construction, except minor renovations to accommodate the installation of the telemedicine equipment. Grant dollars may not be used to acquire or build real property.

- No more than 20% of the grant funds may be used to cover indirect costs associated with the network.

- All grant funds must be used for services provided to or in rural communities and a majority of grant dollars must actually be spent in rural communities for direct services to those communities, including salaries, maintenance of equipment, and transmission costs.

- Grant funds may be used for clinician incentive payments of up to $60 per physician, per consultation, only if no third-party payer *could* be billed for such consultation [added by OAT in 1997].

- Grant dollars may be used to support the development of a business plan as part of the network's required continuation proposal. As a condition on Health System A's receiving grant funding throughout the term of the grant, ORHP must approve

> the business plan (submitted in year two of the grant) to continue the network after the grant term expires [added by OAT in 1997].

Currently, the Telemedicine Network offers interactive and asynchronous telemedicine consultations in thirty-five medical specialties. Health System A has agreements with approximately [over one hundred] physicians to provide telemedicine consultations through the network. Of these physicians, approximately 10% are employed by Health System A; the remainder are on the Health System A hospital medical staff. The greatest number of consultations are provided in the area of mental health, followed by teleradiology and speech pathology.[(9)] The network is also used to provide educational and in-service training programs. The Telemedicine Network is overseen by a project manager and a Telemedicine Advisory Committee consisting of representatives of Health System A and the "spoke" facilities.

In its 1997 grant application, Health System A estimated that it would receive one inpatient admission for every twenty-five telemedicine consultation services it provides to the network. Health System A has represented that apart from the telemedicine equipment funded by the TGP grants and its own payment of line and some maintenance costs, Health System A has not made (and will not make) any payments to, and has not financially supported (and will not financially support), directly or indirectly, telemedicine related services of the other members of the Telemedicine Network or any of their affiliated physicians or health care professionals.

Health System A is currently preparing its business plan for the continuation and expansion of the Telemedicine Network after the grant period expires on August 31, 2000. In general, the network will operate for the same purpose and in the same manner as under the TGP grants. Health System A plans to continue paying for all or part of the transmission line charges related to Telemedicine Network services, with the assistance of third party sources as available.[(10)] In addition, until no later than January 2003, Health System A will continue to pay for maintenance of the telemedicine equipment owned by Health System A and placed at the "spoke" facilities during the grant period.[(11)] Except as provided in the previous sentence, the rural "spoke" facilities will provide their own staffing, space, and maintenance for telemedicine equipment. Existing and new "spoke" facilities will be responsible for the costs of purchasing new or replacement equipment for their respective sites. In some cases, Health System A may purchase telemedicine equipment centrally and lease it to the "spoke" facilities at fair market rental rates pursuant to rental agreements that meet the requirements of the equipment rental safe harbor at 42 C.F.R. º 1001.952(c). Health System A has not paid, and does not intend to pay, any cash or cash equivalent to any "spoke" facility with respect to telemedicine.

C. Federal Reimbursement for Telemedicine Services

A key component of the operation and continuation of the Telemedicine Network is the evolving system of reimbursement for telemedicine services.

Historically, Medicare has reimbursed only those telemedicine applications where, under

conventional health care delivery methods, the medical services do not require face-to-face, "hands on" contact between patient and physician. For example, Medicare has covered teleradiology, the most widely used and reimbursed form of telemedicine, as well as physician interpretation of electrocardiogram and electroencephalogram readings that are transmitted electronically. By contrast, Medicare has not, until recently, covered other physician services delivered through telecommunications systems because under the conventional delivery of medicine, those services are furnished in person. See generally Medicare Program Payment for Teleconsultations in Rural Health Professional Shortage Areas (Proposed Rule), 63 Fed. Reg. 33,882 (June 22, 1998); 63 Fed. Reg. 58,879 (Nov. 2, 1998) (Final Rule).

Under section 4206 of the Balanced Budget Act of 1997 ("BBA") (Pub. L. 105-33), Congress required Medicare Part B, as of January 1, 1999, to begin paying for certain professional consultations via telecommunications systems for beneficiaries residing in rural areas designated as health professional shortage areas ("HPSAs"). Congress further required, among other things, that the payment be shared between the referring practitioner and the consulting practitioner; that the amount of the payment not exceed the current fee schedule amount that would be paid to the consulting practitioner; that the payment *not* include any reimbursement for telephone line charges or facility fees; and that beneficiaries not be billed for any transmission line charges or facility fees (although beneficiaries remain obligated for applicable Medicare copayments and deductibles).

The Health Care Financing Administration ("HCFA") has promulgated regulations implementing section 4206. See 63 Fed. Reg. 58,879, 58,909 (1998) (to be codified at 42 C.F.R. º 410.78). HCFA interprets section 4206 as applying only to interactive patient encounters where the patient is present and the telecommunications technology allows the consulting practitioner to control the interactive medical examination of the patient. Id. at 58,909-10. "Store-and-forward" technologies, like those used in teleradiology, typically do not meet this requirement (although HCFA allows for payment when such technologies are used for interactive patient encounters that meet the teleconsultation requirements). Under the regulations, the practitioner who provides the consultation is paid the applicable physician fee schedule amount and is required to pay 25% of that amount to the referring (e.g., the "spoke") practitioner. The regulations do not provide for any payment of facility fees or technical components to hospitals or other facilities.

Health System A currently receives no reimbursement from any Federal health care program for teleconsultations provided through the network. Given the limitations of section 4206 of BBA and the HCFA regulations (in particular, the requirements that patients reside in HPSAs and that no hospital or facility technical fees are paid), Health System A anticipates receiving limited Medicare reimbursement related to the Telemedicine Network in the future. Health System A may receive some technical fees related to teleradiology services reimbursed under the conventional (i.e., "hands-on" services) rules.

Network practitioners, however, may be paid for telemedicine services in several ways:

- consulting practitioners may receive Medicare payments for interactive consultations under section 4206 of the BBA and the corresponding regulations; the consulting practitioners are required to remit 25% of the fee to the referring practitioners;

- consulting radiologists whose services are not interactive will continue to bill and be reimbursed as they always have for teleradiology services (see generally Medicare Carriers Manual º 2020A); however, referring practitioners receive no Medicare reimbursement related to an interpretation of an x-ray via telecommunications (i.e., the 25% split does not apply);

- as of July 1, 2000, consulting and referring practitioners may be eligible for Medicaid payments pursuant to recently enacted legislation in State X; and

- to the extent no Federal or other third-party payments are available, consulting practitioners may be paid the $60 clinician incentive fee from the 1997 grant funds until the expiration of the grant term in 2000.

II. LAW AND ANALYSIS

The anti-kickback statute makes it a criminal offense knowingly and wilfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by the Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce referrals of items or services paid for by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes 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, in cash or in-kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for 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.), 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. The OIG may also initiate administrative proceedings to exclude persons from Federal health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.[(12)]

We have stated often our view that a gift to an existing or potential referral source that has independent value to such source implicates the anti-kickback statute and may be unlawful if the donor of the gift has the requisite intent to induce Federal health care program referrals. For example, in the preamble to the 1991 safe harbor regulations, we stated that giving a physician who is a referral source a free computer that has independent value to the physician may violate the statute. See 56 Fed. Reg. 35,978 (July

29, 1991); see also, e.g., OIG Advisory Opinion 98-16 (Nov. 3, 1998) (concluding that the provision of free transplant pharmacy services to a transplant center may violate the anti-kickback statute); OIG Special Fraud Alert, 59 Fed. Reg. 65373 (Dec. 19, 1994) (explaining that the anti-kickback statute is implicated if a clinical laboratory provides a phlebotomist to a physician to perform tasks normally the responsibility of the physician's office staff).

With these concerns in mind, in OIG Advisory Opinion 98-18 (Nov. 25, 1998), we concluded that we would not impose sanctions on an arrangement for the provision of telemedicine equipment between an ophthalmologist and an optometrist where the optometrist would pay fair market value (as certified by the requesting party), and the lease would fit in the equipment rental safe harbor. As noted in 98-18, our concern about possible anti-kickback implications extended beyond the value of the equipment itself to the value of the resulting teleconsultations to both the referring and consulting practitioners. In 98-18, these concerns were addressed through certifications that (i) the arrangement would have no independent value to the optometrist, because she would neither use the arrangement for marketing purposes, nor collect a fee for the teleconsultation services, and (ii) the parties had no oral or written collateral agreements or understandings between them, including agreements or understandings regarding the referral of patients from either party to the other.

Despite factual differences, the Arrangement here presents similar kickback concerns. By developing, operating, administering, and funding the Telemedicine Network's telemedicine network (in whole or in part), Health System A confers a benefit on two potential referral sources: (i) the rural "spokes" (and, by extension, the referring health care professionals), which obtain free equipment and subsidized line charges, and (ii) the "hub" consulting practitioners, who receive additional opportunities to earn fees. If one purpose of this remuneration is to induce referrals to a Health System A facility or practitioner, the anti-kickback statute would be implicated.

Notwithstanding, the Telemedicine Network presently operates under the auspices of the TGP, pursuant to a clearly expressed congressional directive to promote telemedicine networks in rural areas, subject to certain statutory limitations and oversight by ORHP/OAT. So long as Health System A is a grant recipient in good standing, and Health System A and the Telemedicine Network satisfy all statutory, regulatory, and administrative grant requirements (including, but not limited to, the expenditure of grant funds and the 24-hour provision of specialty consultations), we do not believe, on the facts presented, that the Arrangement (limited to those aspects described in Part III below) falls into the category of payment practices Congress intended to outlaw under the anti-kickback statute.[(13)]

The continued operation of the Telemedicine Network beyond the grant-funded period is also consistent with congressional intent and the TGP program. However, the absence of applicable grant restrictions and OAT oversight in the post-grant period increases the risk that improper payments for referrals could be masked as payments for telemedicine network purposes. This is especially true where, as here, some parties to the telemedicine

network are engaged in, or contemplating, other joint business relationships.

Under the Arrangement in the post-grant period, payments from Health System A to the "spoke" facilities will be limited to supplemental funding of (i) all or part of the transmission line charges related to the teleconsultation services provided through the Telemedicine Network and (ii) until January 2003, continued maintenance of existing telemedicine equipment owned by Health System A. For everything else, the "spokes" pay their own way, with financial responsibility for all of their own staffing, operational, and maintenance costs, as well as the costs of new or replacement equipment. The "spokes" will remain free (though not necessarily encouraged) to use teleconsultants who are not part of the Telemedicine Network. The Advisory Board will continue to operate in its same capacity.

By subsidizing the Telemedicine Network's transmission line charges and equipment maintenance beyond the grant-funded period, Health System A may in some cases subsidize the private practice incomes of its "hub" consulting practitioners and the referring "spoke" practitioners, many of whom are potential referral sources for Health System A's facilities and providers. Typically these consulting and referring practitioners are not performing a hospital service when they participate in a telemedicine consultation through the Telemedicine Network; rather, they are engaged in their own private medical practices. Absent changes to HCFA's reimbursement rules (under which hospitals are not reimbursed for telemedicine services), if such practitioners are permitted to participate in the network without bearing a "fair share" of its costs, they stand to reap future financial rewards while Health System A bears the corresponding financial burdens. However, we would expect that, at such time as telemedicine becomes financially viable, the practitioners who benefit economically from the Telemedicine Network will also pay their share of its costs.

Finally and importantly, the Arrangement presents an opportunity for significant community benefit through the study and development of telemedicine as a mechanism to (i) improve access to essential health care services (including preventive and emergency services) for rural patients who may otherwise forgo care; (ii) constrain health care costs in rural areas; and (iii) reduce the isolation of rural health care professionals.

Given all of the facts and circumstances, including, without limitation, (i) the clear congressional policy favoring the study and development of rural telemedicine networks, (ii) the oversight of the Telemedicine Network by ORHP/OAT during the grant period, (iii) Health System A's representation that it has complied fully (and will continue to comply fully) with the terms of its TGP grants, (iv) the comprehensive range of telemedicine services provided through the network, (v) the limited remuneration during the post-grant period, and (vi) the significant potential community benefit to rural citizens through increased access to health care, we conclude that we would not impose sanctions on Health System A for violations of the anti-kickback statute arising from the Arrangement.

III. CONCLUSION

Based on the information provided, we conclude that the Arrangement (as defined in the next sentence) could potentially involve prohibited remuneration under section 1128B(b) of the Act, if the requisite intent to induce referrals were present; however, the Office of Inspector General ("OIG") will not impose sanctions on Health System A for violations of the anti-kickback statute arising under sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Arrangement (limited as set forth in the next sentence), as described and certified in the request letter and supplemental submissions. For purposes of this paragraph, the "Arrangement" means, collectively, Health System A's (i) use of Federal grant funds under the terms of the ORHP/OAT grants; (ii) continued provision of telemedicine consultations within the Telemedicine Network after the end of the grant period; (iii) continued payment of transmission line charges related to the Telemedicine Network (whether by Health System A or third party sources arranged for by Health System A) after the end of the grant period; (iv) continued payments after the end of the grant period to an unrelated third-party vendor to maintain the existing telemedicine equipment owned by Health System A until January 2003; (v) lease of telemedicine equipment to members of the Telemedicine Network pursuant to leases that satisfy the equipment rental safe harbor at 42 C.F.R. º 1001.952(d) after the end of the grant period; and (vi) participation in the administration of the Telemedicine Network for telemedicine purposes after the end of the grant period.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to the Health System A, the requester 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 requester to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to Health System A or any other party involved in the Arrangement.

- 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 that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the requester with respect to any action that is part of the 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 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, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the requester 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 the Arrangement in practice comported with the information provided 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,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General

1. No opinion is expressed or implied with respect to any other relationship between or among the Telemedicine Network members or any other party. Except as it relates to the relationship between Health System A and the Telemedicine Network members, no opinion is expressed or implied with respect to the legality of the maintenance contract between Health System A and the vendor.

2. The Office of Rural Health Policy ("ORHP") preceded the Office for the Advancement of Telehealth ("OAT"). For purposes of this advisory opinion, references to the ORHP should be considered synonymous with the present OAT.

3. Pursuant to the 1994 Program Guide, an entity was capable of providing 24-hour consultations if it had relevant specialists on-call. See 1994 TGP Program Guide at 3.

4. Grant applicants had to agree to obtain prior approval from ORHP before altering the network's membership.

5. Telemedicine Network is a consortium of hospitals and clinics, but not a separately incorporated legal entity. The members of Telemedicine Network or their affiliates may be engaged in, or contemplating, other joint business relationships. Those relationships are outside the scope of this advisory opinion.

6. The facilities are: [names and locations redacted]

7. Because it is not a legal entity, the Telemedicine Network was ineligible to serve as a grant recipient. Nor could any of the "spokes" qualify as grant recipients, because none provided the required multi-specialty, 24-hour consultations.

8. The telemedicine equipment may also be used, and is used, by health care professionals at the "spoke" facilities to communicate and consult with one another and with practitioners not affiliated with Telemedicine Network.

9. In the initial years, teleradiology played a small role in the Telemedicine Network, although it was a core required service for the 1994 grant. Of the original [# redacted] physicians who agreed to provide consultations, only [# redacted] were radiologists, and the Telemedicine Network didn't begin teleradiology services until April 1998. Because of certain limitations of available technology (e.g., resolution of transmissions), grant-funded teleradiology equipment has been installed in only one spoke facility. However, Telemedicine Network may expand its teleradiology capabilities using TGP grant funds to purchase and place teleradiology equipment in the "spoke" facilities.

10. Health System A expects that the Telemedicine Network's transmission line charges may be reduced by as much as 60% as a result of the Universal Service Fund ("USF") provisions of the Telecommunications Act of 1996 and recent Federal Communications Commission rulings addressing rural telecommunications rates. Telemedicine Network's application for USF funding has been approved.

11. Specifically, Health System A will pay a fixed fee to an unrelated, third party vendor for maintenance services. This vendor is the only vendor in the area that services the specific telemedicine equipment, and Health System A expects that the vendor will cease providing parts and servicing for the equipment by January 2003.

12. Because both the criminal and administrative sanctions related to the anti-kickback implications of the Arrangement are based on violations of the anti-kickback statute, the analysis for the purposes of this advisory opinion is the same under both.

13. This opinion is limited to the facts presented. Circumstances may exist in which parties use Federal grant programs or funds to further fraudulent or abusive schemes. This opinion should not be construed as standing for the proposition that the use of Federal grant programs or funds immunizes a party from sanction under the anti-kickback statute.