

[We have redacted specific information regarding the requester and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise specified by the requester.]

Issued: September 30, 1999

Posted: October 7, 1999

[Name & Address Redacted]

Re: OIG Advisory Opinion No. 99-9

Dear [Name Redacted]:

We are writing in response to your request for an advisory opinion about a proposed contractual arrangement between a self-insured employer health plan and a single-specialty managed care organization to provide managed podiatry benefits for the employer's retirees (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for sanctions under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), or under the civil money penalty provision for inducements to beneficiaries, section 1128A(a)(5) of the Act, in the circumstances presented.

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 and subject to certain conditions described below, we conclude that (i) the Proposed Arrangement could involve prohibited remuneration under section 1128B(b) of the Act, if the requisite intent to induce referrals were present, but that the Office of Inspector General ("OIG") will not impose sanctions on Corporation A, pursuant to the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Proposed Arrangement; and (ii) the OIG will not subject Corporation A to sanctions under section 1128A(a)(5) of the Act in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than Corporation A, the requester of this opinion, and is further qualified as set out in Part V below and in 42 C.F.R. Part 1008.

I. BACKGROUND

A. Corporation A

Corporation A, (the "Plan") is a State X corporation in the business since [year redacted] of providing specialized management of podiatry benefits for self-insured employer plans. The Plan is licensed in State X as a health care alternative financing and delivery system. As such, its operations are subject to regulation under the State X HMO Act by the State X Insurance Bureau and the State X Department of Community Health. The Plan is not owned or controlled by podiatrists or any organization affiliated with podiatrists, nor are there podiatrists on the Plan's Board of Directors. The Plan employs podiatrists as medical directors.

The Plan has provided Corporation B (now known as [name redacted]) (the "Employer") with managed podiatry benefits for its employees for over sixteen years (the "Employee Program").⁽¹⁾ As a result of the Employee Program, the Employer has experienced significant cost savings and reductions in abuses related to podiatry benefits, including overutilization and inappropriate treatment. For example, the Employer has represented that it saved \$3.4 million in health care benefits related to foot care in one state during the first two years of the Employee Program and that it also experienced significant reductions in disability and sick leave expenditures related to foot care.

B. The Proposed Arrangement

The Plan proposes entering into a new arrangement with the Employer to provide similar managed podiatry benefits for the Employer's retirees (the "Retiree Program" or the "Proposed Arrangement"). Most retirees covered by the Employer's health plan are Medicare fee-for-service beneficiaries for whom the Employer acts as a supplemental insurer, paying their Medicare deductibles and copayments (collectively, "Medicare cost-sharing") on a per-claim basis. The Employer engages in little or no utilization review of such cost-sharing claims. Through the Retiree Program, the Employer anticipates reducing its expenditures on Medicare cost-sharing for podiatry services, while simultaneously offering retirees more covered podiatry benefits. The Retiree Program will be identical to the Employee Program in all material respects, including the scope of covered benefits and controls on utilization of services with the exception of the Retiree Program's interplay with the Medicare Program (for which there is no Employee Program counterpart) and the enhancement of the utilization review program as discussed elsewhere in this letter. The Union has been, and remains, involved in the decision to adopt the Retiree Program and in the related approval process.

Under the Proposed Arrangement, the Employer will pay the Plan annually a fixed, capitated fee. The fee will reflect the Employer's historic annual expenditures for Medicare cost-sharing, discounted by an amount estimated to reflect the projected reduction in utilization of foot care services under the Retiree Program.

In exchange for this fee, the Plan will assume full financial risk for all Medicare cost-sharing and all administrative costs in connection with the provision of all medically necessary foot care services for the Employer's retirees, except for inpatient facility services and services within the first seventy-two hours related to accidental injuries (including fractures and sprains), which will continue to be covered under the Employer's regular health insurance benefit. In essence, the Plan will assume the Employer's role of supplemental insurer for the retirees, thus taking on the obligation to pay Medicare cost-sharing amounts to individual providers.

The Plan contracts with a network of approximately 3,300 credentialed podiatrists and other physicians and providers nationwide (the "Network Providers"), most of whom will be required to participate in both the Employee and Retiree Programs.⁽²⁾ The Network Providers will participate in the Retiree Program pursuant to one-year written contracts. In establishing the financial terms of the Retiree Program, neither the Plan nor the Network Providers have given or received, or will give or receive, a discount on the Employee Program's financial terms.

The Plan will pay the Medicare cost-sharing amounts on a per-claim basis for all non-routine professional services, and all outpatient facility services, treatment by subspecialists, anesthesiology, and other specialized or supplemental services, bone scans, and other diagnostic tests (except x-rays) (the "Retained-Risk" services) to the extent they are covered by Medicare.⁽³⁾

The Plan will also pay Network Providers a capitated amount per enrollee that will cover any Medicare cost-sharing for routine professional podiatric services (i.e., Medicare reimbursable podiatric services other than the Retained-Risk services), as well as additional services which are not typically covered by Medicare. These additional services include routine office visits, preventive care, and orthotics (the "Additional Services"). With respect to Medicare-reimbursable services covered by the capitated amount, the Network Providers will bill Medicare on a fee-for-service basis and accept the capitation in lieu of collecting Medicare cost-sharing amounts from the Employer or the retirees. The Network Providers will be required to submit to the Plan's utilization control mechanisms for services payable by the Medicare program.

The Plan will assign retirees to Network Providers on a geographical basis, allocating them among Network Providers within zip code areas. A retiree will be able to obtain services from a provider other than his or her assigned Network Provider, including providers outside the network, but would then be responsible for paying Medicare cost-sharing amounts up to an out-of-pocket maximum.⁽⁴⁾ The Plan will pay Medicare cost-sharing amounts over the out-of-pocket maximum in full. Retirees who reside more than twenty-five miles from the nearest Network Provider will be allowed to obtain services out-of-network at no cost to the retiree.

C. The Proposed Arrangement's UR/QA Program

The Plan's extensive utilization review and quality assurance programs for the Employee Program (collectively, the "UR/QA program") will be expanded to apply equally to the Retiree Program. The UR/QA program consists of two parts: a pre-certification requirement applicable to surgeries and referrals to hospitals or outpatient surgery centers and an "adjudication system" for routine office visits and preventive care services.

The pre-certification procedure for surgeries and referrals to hospitals or outpatient surgery centers uses medical necessity guidelines developed by the Plan. If a provider or patient disagrees with a pre-certification determination, a peer review procedure is in place that includes review by a panel of independent physicians and podiatrists, whose determination is honored. Under the Retiree Program, Network Providers will not be allowed to bill Medicare for any covered foot care service for which pre-certification is required but not obtained.⁽⁵⁾ Network Providers must also participate in certain other quality of care and educational programs designed to detect and correct patterns of overutilization or other inappropriate practices. In addition, the Plan is considering establishing a funds withholding and risk pool arrangement as an additional incentive to Network Providers to cooperate with the pre-certification requirements and the restrictions on billing Medicare.

The second component of the UR/QA program -- the "adjudication system" -- applies to services that are not subject to pre-certification, primarily services provided during routine office visits. Under the adjudication system, Network Providers submit monthly encounter data reports, which are reviewed by the Plan's management, including its medical director. The utilization reports identify utilization rates for all procedures, including those for which the Network Providers are at risk under the capitation. The Plan uses the encounter data to identify Network Providers whose use of a procedure is significantly above or below the median utilization of the procedure by all Network Providers, using statistically valid methods and taking into account geographical considerations and recognized medical standards.

The Plan employs a system of random audits and surveys to verify compliance with the UR/QA program. In addition, the Plan randomly selects 100 claims each month for review of clerical accuracy, CPT code accuracy, medical necessity, and appropriateness of care. The Plan will make available to the Health Care Financing Administration, upon request, all records relating to these audits and surveys, as well as other utilization and quality control information in connection with the Retiree Program.

Network Providers identified by the Plan as significantly under- or overutilizing a procedure are subject to counseling, corrective action, or dismissal from the network. The enforcement process consists of education and counseling, a probationary period during which the Network Provider's data is monitored, and, if the Network Provider fails to adhere to reasonable norms, termination of his or her contract. For the period from January 1997 until April 1999, the Plan counseled a total of eighty-eight Network Providers and terminated twenty-one for overutilization. In particular, four Network Providers were terminated for overutilization of services covered solely by the Plan's capitated payment, even though the Plan incurred no financial loss.

In combination, the pre-certification and adjudication systems will subject virtually all Medicare-covered services to utilization review. To ensure effective review of Medicare-covered services, the UR/QA program will be applied identically in the Employee and Retiree Programs and "blinded" so that reviewing personnel will not know whether the patient is an employee -- for whom the Employer pays under the Employee Program -- or a retiree -- for whom Medicare is primarily at risk.

To further protect the Medicare program from provider attempts to circumvent the UR/QA program, the Plan will obtain information from fiscal intermediaries about procedures performed by Network Providers and billed to Medicare. The Plan will conduct random utilization management audits of the information to identify any Network Providers who are not submitting encounter reports for all procedures performed on Medicare enrollees or who are not cooperating with the pre-certification requirements. The information will also be used to identify charts to be pulled in random audits. The confidentiality of patient records will be protected.

Finally, the Plan plans to develop guidelines applicable to procedures for which pre-certification will not be required under the Retiree Program, but that are subject to abuse or should be monitored for other reasons. For example, independent of the Proposed Arrangement, the Plan is developing a guideline for conservative treatment of mycotic toenails, an area the Plan has identified as problematic in the Employee Program and an area that has led to abuses in the Medicare program.

D. Medicare Reimbursement

Medically necessary foot care services are covered under Part A and Part B of Medicare; however, routine foot care services are generally excluded from coverage, as are most orthopedic shoes and other supportive devices. See 42 U.S.C. §§ 1395y(a)(8) & (13). Limited orthotics are covered for some diabetic patients. In addition, Medicare covers a limited number of routine services, such as treatment of mycotic toenails, which are only covered when a patient has a systemic disease of sufficient severity that unskilled performance of such a procedure would be hazardous. See, e.g., Medicare Carriers Manual § 4120.1.

II. ALTHOUGH THE PROPOSED ARRANGEMENT POTENTIALLY IMPLICATES THE ANTI-KICKBACK STATUTE, THE OIG WILL NOT IMPOSE SANCTIONS.

A. Law

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 (3rd 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. This Office 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. [\(6\)](#)

There are several statutory exceptions and regulatory "safe harbors" under the anti-kickback statute. As a threshold matter, the Proposed Arrangement is not protected by the exception to the anti-kickback statute for certain risk-sharing arrangements, section 1128B(b)(3)(F) of the Act. Although similar in some respects to managed care arrangements addressed by that exception, the Proposed Arrangement will not be implemented pursuant to a contract with Medicare or a State health care program, nor will the Plan or its providers be put at substantial financial risk for the cost or utilization of items or services provided to Federal health care program beneficiaries. Similarly, the Proposed Arrangement does not come within the definition of a protected health plan under the existing regulatory safe harbor for increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans, 42 C.F.R. § 1001.952(*I*), which requires that a protected health plan have a contract with the Health Care Financing Administration.

The OIG's concern about the potential for fraud and abuse arising from the routine waiver of Medicare cost-sharing amounts is longstanding. See, e.g., Preamble to Final Rule on Safe Harbors for Protecting Health Plans, 61 Fed. Reg. 2122, 2124 (Jan. 25, 1996); Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B, 59 Fed. Reg. 35373, 35374 (Dec. 19, 1994). Such waivers undermine the important utilization and cost control functions of the cost-sharing requirement.

We have also previously articulated our concern that agreements between providers and health plans to forgo cost-sharing amounts may result in kickbacks from providers to health care plans in exchange for referrals of Federal program business. For example, the preamble to the 1996 Final Rule establishing certain managed care safe harbors explained that:

"[t]he [anti-kickback] statute prohibits any remuneration which is in return for, or which is designed to induce, the flow of Medicare and Medicaid program-related business. Therefore, it could cover a hospital's agreement to forego or reduce coinsurance or deductibles in exchange for increased program-related business. It does not matter that the payment is made to a third party rather than the beneficiary." 61 Fed. Reg. 2124; see also OIG Advisory Opinion 98-5 (Apr. 17, 1998).

B. Analysis

The principal issue raised by the Proposed Arrangement is whether, in exchange for the Employer's retiree business, the Plan and its Network Providers will be giving the Employer a discount on the Medicare copayment obligation the Employer would otherwise have to satisfy on behalf of its Medicare-eligible retirees. Since a reduction in an amount legally owed confers a financial benefit on the party receiving the reduction, full or partial waivers of Medicare copayment obligations used to attract business have long been suspect under the anti-kickback statute.

The Proposed Arrangement is similar in some respects to the arrangement that raised substantial concerns under the anti-kickback statute in OIG Advisory Opinion 98-5. In that arrangement, a nursing home entered into an agreement with a health care plan to accept the health care plan's per diem amount as payment in full for services rendered to all plan members, including retirees for whom Medicare was the primary payer and the plan was only secondarily liable. For those plan members who were Medicare beneficiaries, the contractual arrangement effectively required the nursing home to forgo certain Medicare cost-sharing amounts that the health care plan would otherwise have had to pay on behalf of its retiree beneficiaries. We concluded that the arrangement potentially violated the anti-kickback statute.

One of our concerns about the arrangement in OIG Advisory Opinion 98-5 was that the nursing home's willingness to forgo cost-sharing revenue was, in essence, a price concession offered to the health plan in exchange for the opportunity to treat the health plan's Medicare population. By releasing the health plan from its obligation to pay the Medicare copayment, the arrangement posed an increased risk of overutilization and increased program costs by eliminating the health plan's financial incentive to control the level and intensity of health care services provided to Medicare beneficiaries. In effect, the nursing home agreed to provide care to plan members paid for by the plan at a low price (including savings on copayments) in exchange for referrals of Medicare beneficiaries paid for by Medicare. See also OIG Advisory Opinion 99-2 (Feb. 26, 1999).

The Proposed Arrangement is different from the suspect arrangement in OIG Advisory Opinion 98-5. Most importantly, the Employer will pay the full amount of its projected copayment obligation for podiatry services for its retirees. Similarly, the contracted Network Providers, in the aggregate, will receive their full anticipated copayment amounts minus only an amount to fund the Plan's operating expenses. In other words, there may be no waiver of any Employer copayment obligation.

A key to determining the adequacy of the Employer's payment is an assessment of the effectiveness of the Plan's management of the podiatric network and services. Many utilization review and quality assurance activities are of questionable benefit in controlling unnecessary utilization and containing health care costs. For example, many programs are of the "pay-and-chase" variety, reviewing utilization either retrospectively or concurrently (rather than prospectively). Moreover, most utilization programs rely primarily on identifying providers with aberrant utilization patterns (i.e., extreme outliers compared to other providers); these programs do not address the situation of a physician or physicians routinely providing medically unnecessary care without exceeding the "aberrant" threshold. For these and other reasons, utilization review programs have limited effectiveness as fraud and abuse controls.

There is substantial evidence, however, that the Proposed Arrangement's UR/QA program offers meaningful review. For example:

- The identical program (i.e., the Employee Program) has been in effect for over sixteen years and has been effective in reducing utilization among the Employer's active workers. Accordingly, the Employer has a reasonable historical experience with virtually the identical program upon which to assess anticipated utilization and corresponding copayment obligations.
- The review process will be blinded so that services provided to Medicare retirees will be reviewed in the same manner and subject to the same standards as services provided to employees for whom the Employer is fully liable under the Employee Program.
- Virtually all of the Retained-Risk services billed to Medicare (accounting for approximately 70% of Medicare's dollar volume for podiatry services) will be subject to pre-certification. In other words, the medical necessity of these services will be evaluated prospectively based on the particular circumstances of each case.
- The program has an established record in tracking, monitoring, and disciplining podiatrists who fail to adhere to the UR/QA program guidelines and protocols, even in circumstances where the Plan has not been at-risk for the cost of the services.
- Because the Plan is not a provider-sponsored or controlled organization, it has an arms-length relationship with its Network Providers and no incentive to manipulate the UR/QA system to benefit them.
- The pre-certification protocols and the additional guideline for mycotic toenails have been reviewed and approved for appropriateness by an outside expert pursuant to the provisions of 42 C.F.R. § 1008.33.⁽⁷⁾

In light of these characteristics, it is reasonable to conclude that (i) the Proposed Arrangement is likely to result in a reduction in unnecessary podiatry services and (ii) the Employer payment to the Plan will substantially approximate its applicable copayment obligation in the aggregate.

Moreover, even if some part of the copayment obligation would be waived, we would not impose sanctions on the Plan in connection with such waiver in light of the overall structure of the UR/QA program, the fact that the Proposed Arrangement is very likely to result in a reduction in Federal health care expenditures, and the potential for increased benefits to Medicare beneficiaries.

Simply put, for every dollar that the Employer saves in Medicare copayments through elimination of unnecessary foot care for retirees, the Federal government saves four dollars. Thus, even if the copayment match is only roughly approximate, the Proposed Arrangement is likely to confer a substantial financial benefit on the Federal fisc as the primary beneficiary of the Plan's management of the foot care benefit.

In addition, the Proposed Arrangement is likely to benefit Federal beneficiaries through access to expanded insurance coverage for the Additional Services. The Proposed Arrangement preserves freedom of choice for Medicare beneficiaries through the out-of-network alternative, which permits retirees to select any provider. Retiree interests are further protected through the participation of the Union as a collective bargaining agent.

Finally, the Proposed Arrangement preserves the primary purpose of Medicare copayments as a check on unnecessary utilization. Copayments encourage responsible use of health care services by giving beneficiaries a financial stake in their health care. This function is undermined when beneficiaries obtain supplemental insurance coverage for cost-sharing amounts through employer plans or Medigap policies, since those beneficiaries have no financial incentive to reduce utilization. Like the Employer under its current practice, most employer plans and Medigap insurers engage in little or no utilization review of Medicare copayment claims since such review is not cost effective given the plans' relatively limited financial exposure for any given service. By establishing a Retiree Program comparable to its existing Employee Program, the Employer will be using its cost-sharing dollars for their intended purpose: to encourage efficient and judicious use of foot care services paid for by Medicare.

We recognize that, despite the safeguards incorporated into the Proposed Arrangement, there may be "rogue" providers who bill for medically unnecessary services, upcode claims, bill for services not provided, or engage in similar illegal activities. Nothing in this advisory opinion protects such providers or activities or limits the OIG's ability to enforce the Federal anti-fraud and abuse authorities against such unscrupulous providers.

III. THE OIG WILL NOT SUBJECT THE PLAN TO CIVIL MONEY PENALTIES UNDER SECTION 1128A(a)(5) OF THE ACT IN CONNECTION WITH THE PROPOSED ARRANGEMENT.

A further question arises as to whether the Additional Services provided to Medicare beneficiaries violate section 1128A(a)(5) of the Act, which prohibits a person from offering or transferring remuneration to a beneficiary that such person knows or should know is likely to influence the beneficiary to order items or services from a particular provider or supplier for which payment may be made under the Medicare and Medicaid programs. The Plan will offer the Additional Services to retirees to induce them to use the managed services network generally. All Network Providers will offer the Additional Services, and thus the services will not be an incentive to choose a particular provider within the network. For these reasons, the OIG will not subject the Plan to sanctions under section 1128A(a)(5) of the Act in connection with the Proposed Arrangement.

IV. CONCLUSION

For the above-stated reasons and based on the facts as certified in the request letter and supplemental submissions, we conclude that (i) the Proposed Arrangement could involve prohibited remuneration under section 1128B(b) of the Act, if the requisite intent to induce referrals were present, but that the OIG will not impose sanctions on the requester pursuant to the anti-kickback statute under sections 1128(b)(7) and 1128A(a)(7) of the Act in connection with the Proposed Arrangement; and (ii) the OIG will not subject the Plan to sanctions under section 1128A(a)(5) of the Act in connection with the Proposed Arrangement.

V. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to the Plan, 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 the Plan or any other party involved in the Proposed Arrangement.
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- 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 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, 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 Proposed 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

FOOTNOTES:

1. The Employer sponsors health plans for its employees and retirees pursuant to collective bargaining agreements with Union Y (the "Union").
2. There are limited exceptions for certain providers who do not wish to participate in the Retiree Program, but who are needed to provide adequate coverage under the Employee Program in areas with few alternative providers.
3. The Retained-Risk services include most of the procedures described in the top twenty Medicare procedure codes shown on the State X Medicare Part B Procedure Code Analysis by Speciality (#48-Podiatry) published by the Health Care Service Corporation and submitted by the Plan, accounting for approximately 74% of Medicare's dollar volume relating to procedures that may be performed by podiatrists.
4. The amount of the out-of-pocket maximum will be subject to the Union's concurrence.
5. The Plan currently has pre-certification requirements and guidelines in place for approximately 325 of the 500 procedure codes for which Medicare will pay podiatrists, or approximately 65% of the total number of applicable Medicare codes. The remaining codes are primarily for routine care, office visits, and preventive care, many of which are not covered by Medicare. Using existing guidelines, the Plan will control and pre-certify most of the procedures described in the top twenty Medicare podiatry procedure codes, accounting for approximately 74% of Medicare's dollar volume relating to procedures that may be performed by podiatrists. The guidelines will be expanded over the next two years to cover all of the top twenty codes and substantially all of the top fifty (which account for 91.6% of total Medicare dollars paid for podiatry services). See State X Medicare Part B Procedure Code Analysis by Speciality (#48-Podiatry).
6. 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.
7. In reviewing the Plan's UR/QA program for purposes of this advisory opinion, we looked at whether the program was likely to be effective in reducing utilization and whether it would be likely to result in denials of medically necessary care. Determinations made by the Plan or the UR/QA program with respect to a Network Provider's utilization are not, and will not be, binding on the OIG in any enforcement action.