[*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*.]

[Posted: June 27, 2000]

[Issued: June 20, 2000]

Dr. Neil F. Gordon
INTERxVENT[USA], Inc.
340 Eisenhower Drive
1400 Central Park, Suite 17
Savannah, GA 31406

Re: OIG Advisory Opinion No. 00-4

Dear Dr. Gordon:

We are writing in response to your request for an advisory opinion concerning a lifestyle modification program for individuals with chronic disease that uses physicians to monitor and evaluate the program's participants (the "Proposed Arrangement" or the "Program"). Specifically, you have inquired whether the Proposed Arrangement constitutes grounds for sanctions under the anti-kickback statute, section 1128B(b) of the Social Security Act (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 Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that, based on the totality of the facts as described and certified in your request letter and supplemental submissions, the Office of Inspector General ("OIG") will not subject INTERxVENT[USA], Inc., to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than INTERxVENT[USA], Inc., and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

INTERxVENT[USA], Inc. ("INTERxVENT" or the "Requestor"), has created the Program, a coordinated lifestyle and behavior modification program that focuses on nutrition, exercise, smoking cessation, and stress management for individuals with, or at risk for, certain chronic diseases (the "Participants"). Most Participants have, or are at risk for, cardiovascular disease or stroke. In essence, the Proposed Arrangement is a preventive health program for chronic disease patients.

The following aspects of the Program are described below: (i) the Program's services; (ii) the Program's physician network; and (iii) payment for the Program's services.

A. The Program's Services

The core of the Program's services is an individualized "risk reduction" program. INTERxVENT has created a computer program that will generate a set of "risk reduction goals" and a "personal action plan" for each Participant, based on guidelines set by the American Heart Association, the American College of Cardiology, the U.S. Public Health Service Preventive Services Task Force, and other national organizations. The INTERxVENT

computer program uses information from questionnaires that each Participant must complete on his or her medical history and health habits, in addition to certain other data, such as the Participant's weight and blood pressure. The Program reinforces the lifestyle changes specified in the personal action plans by requiring the Participants' attendance at regular meetings with non-physician health care professionals ("Mentors"), such as nurses, physical therapists, exercise physiologists, and dietitians. Mentors counsel the Participants on how to alter their nutrition, exercise, and other lifestyle habits, and thereby improve their health.

Using the risk reduction goals and the personal action plan as a guide, each Participant visits a Mentor approximately twenty times during the first year of enrollment in the Program. After the first year, the Participants visit their Mentors approximately twelve times per year (once per month). During each visit, the Mentor works with the Participant using various behavior modification techniques. Participants are required to keep diet and exercise diaries that the Mentors check during each visit. The Program uses a computerized system to manage and track the Participants' compliance with the action plan.

Occasionally, where clinical intervention is indicated based on medical guidelines, the Mentors may refer Participants to physicians to help the Participants meet their risk reduction goals. A Participant may be referred to a physician to consider testing (e.g., a blood test for cholesterol and triglyceride levels) and drug therapy (e.g., prescribing cholesterol lowering drugs, anti-hypertensive agents, oral hypoglycemic agents, hormone replacement therapy, etc.). Generally, these referrals will be to the Participant's own personal physician. However, if a Participant does not have a personal physician, the Participant may choose a physician from a list of physicians in INTERxVENT's physician network ("Network Physicians"), as described below. For Participants who would like INTERxVENT to recommend a specific physician, one will be chosen from the list based on geographic proximity, on a rotating basis.

An integral part of the Program is INTERxVENT's ongoing research study, in which Participants are required to participate. An objective of the study is to follow patients with, or at risk for, chronic disease treated in community-based physician practices, tracking the effect of changes in nutrition, exercise, and other lifestyle habits on their conditions.

B. The Physician Network

Participants may access the Program's services in one of three ways: (i) through an institution (e.g., an employer or a managed care plan); (ii) through self-referral to the Program; or (iii) through Network Physicians.(1) Relevant to this opinion are only the Program's aspects that involve the Network Physicians.

Network Physicians are usually cardiologists, primary care physicians, and internal medicine physicians to whom INTERxVENT has marketed the Program as a low cost, high benefit behavior modification program that physicians can offer to their patients with, or at risk for, chronic disease as an adjunct to their medical care. In most cases, the Network Physicians will be referring their own patients to participate in the Program, rather than receiving new referrals from the Program. New referrals of patients from the Program will be rare because under the Program, if a Participant needs a referral to a physician, Participants are referred first to their personal physician. Thus, most of the referrals from the Program to the Network Physicians will be their own patients returning for check-ups or for possible testing or changes to their medication in accordance with national medical guidelines.

The Network Physicians periodically will evaluate the Participants that they refer to the Program. In most cases, the INTERxVENT Mentor will guide the Participants through the questionnaires and will take the various measurements needed to evaluate the Participants' progress and generate reports. However, the Network Physicians will review and sign the action plans, risk reduction goals, and progress reports that are generated, and will modify them as needed. The Program will pay the physicians $[ ] for the initial evaluation report and $[ ] for each subsequent re-evaluation report.

Each Network Physician will pay INTERxVENT a participation fee of $[ ] initially and thereafter will pay a $[ ] annual fee. Occasionally, these fees may be discounted or waived based on sponsorship of the physician or physician group by a JCAHO accredited health system, the number of their patients who participate in the

program, and the number of patients who meet their goals. The fee will cover the costs of Program materials, computer software, and free or discounted participation in the Program for the Network Physician's employees (as described below).

C. Payment for the Program's Services

In general, a Participant pays out of pocket for the Program's services; however, if the Participant is enrolled through an institution, such as an employer or a managed care plan, then the institution may pay on the Participant's behalf. In either situation, a key to the Program is keeping the costs of participation low.

In general, Participants pay $[ ] per year to enroll in the Program, subject to the following discounts. First, all employees of Network Physicians may attend the Program's orientation session and initial evaluation session free of charge. In addition, up to five of a Network Physician's employees may enroll in the Program free of charge; any additional employees may participate in the Program at a discounted rate of $[ ] per Participant per year.

Second, if the Participant enrolls in the Program through an institution, the Program currently charges the institution at a rate of $X per Participant per year, or $Y per identified high risk covered person per year. The $Y fee is collected regardless of whether the Program is actually used. Such institutions may include Medicare Plus Choice organizations, with which INTERxVENT may contract to provide the Program's services to the plans' at risk chronic disease patient population.(2) At present, INTERxVENT does not have any contracts with Medicare Plus Choice organizations.

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 referrals of items or services reimbursable by any Federal health care program. See section 1128B(b) of the Act. Specifically, the statute provides that:

> Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony.

Id. Thus, where remuneration is paid purposefully to induce referrals of items or services for which payment may be made 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, 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 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.), 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 and State 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.(3)

B. Analysis

The Proposed Arrangement raises the following two issues under the anti-kickback statute: (i) whether the Network Physicians will pay participation fees to INTERxVENT in exchange for INTERxVENT's referrals of patients to the Network Physicians for Federal health care program-covered services; and (ii) whether INTERxVENT will pay the Network Physicians fees in exchange for the Network Physicians' referrals of patients whose Program services may be paid for by the Federal health care programs.

The Proposed Arrangement poses a minimal risk of fraud or abuse for the following reasons:

- The Network Physicians pay INTERxVENT's initial and annual participation fee payments to offer their patients access to the Program and to offer their employees the benefit of free or discounted Program services. The Network Physicians only occasionally will receive referrals from INTERxVENT. Moreover, when a Network Physician receives a referral, in most cases the referral will be of a Participant who was originally the Network Physician's own patient. The Network Physician would perform services on these patients that generally would be performed at a regular check-up. A very small number of referrals from INTERxVENT to the Network Physicians will be new patients.
- The Program will not increase Federal health care program costs. The vast majority of Participants will pay for the Program's services out of their own pockets or will have employers who will pay for them. Although currently INTERxVENT does not have any agreements negotiated with Medicare Plus Choice organizations for coverage of the Participants' enrollment fees, in the future, some Participants may have the Program's enrollment fees covered by their Medicare Plus Choice plans. However, because the Federal health care programs pay Medicare Plus Choice plans a capitated rate, a plan's decision to cover enrollment fees will not increase Federal health care program costs.[(4)]

As a result, the Program poses a minimal risk of fraud or abuse. Furthermore, the Program potentially offers significant benefits to individuals with chronic disease. The Program is designed to improve patient compliance with risk reduction programs, thereby potentially improving their health and reducing Federal health care program costs. In addition, the Program will enable INTERxVENT to conduct independent research on the effect of preventive measures on patients whose chronic diseases are being managed clinically in individual community-based physician practices.

For these reasons, we would not impose sanctions on the Requestor arising under the anti-kickback statute, section 1128B(b) of the Act.

III. CONCLUSION

Based on the information provided, we conclude that the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that, based on the totality of the facts present in the Proposed Arrangement as described and certified in the request letter and supplemental submissions, the OIG will not subject the Requestor to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Proposed Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to INTERxVENT^{USA}, Inc., 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 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 Proposed 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 requestor 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 requestors 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,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General

1. In rare cases, a physician group may obtain a license from INTERxVENT to run its own Program. However, in such cases, the individual physicians in the group are not Network Physicians and receive no money from INTERxVENT.

2. The Medicare Plus Choice Plan may provide the Program's services through, for example, a cardiac rehabilitation provider.

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

4. The safe harbor for price reductions offered to eligible managed care organizations, 42 C.F.R. § 1001.952(t)(i), may apply to arrangements between INTERxVENT and Medicare Plus Choice organizations. However, because INTERxVENT is not proposing to enter into any arrangements with specific Medicare Plus Choice organizations, we will not opine on whether such an arrangement would meet the safe harbor's requirements.