*Response:* We agree with the first commenter. A financial relationship may exist in the form of an ownership or investment interest, which, according to the language in section 1877(a)(2), "may be through equity, debt, or other means." We did not propose any exceptions addressing situations involving debt. That is because we do not believe that there would be no risk of program or patient abuse in such circumstances. Obviously, the continued financial viability of an entity that is in debt to a potential referring physician could be of great concern to that physician. Therefore, we are not providing the exception requested.

Comment: Two commenters indicated that the term "indirect relationship," which is used to define financial relationships in proposed § 411.351, should be itself defined or deleted since there is no statutory definition of indirect relationships. According to the discussion at page 8595 of the proposed rule's preamble, "a physician would be considered to have an indirect financial relationship with a laboratory entity if he or she had an ownership interest in an entity which in turn has an ownership interest in the laboratory entity." The commenter stated that, if this is the definition we adopt, that definition should appear in §411.351 of the final regulations; otherwise, the term should be deleted from the regulation entirely.

Response: We agree with the commenter that our interpretation of indirect ownership or investment interest should appear in the regulation. Therefore, we include it in section 411.351 of this final rule. As specified at section 1877(a)(2), financial relationships that could cause a referral to be prohibited are of two kinds. The first is an ownership or investment interest, which may be through equity, debt, or other means. The second is a compensation arrangement, which, as defined at section 1877(h)(1)(A), is any arrangement involving any remuneration (with certain narrow exceptions added by OBRA '93). "Remuneration" is defined in section 1877(h)(1)(B) as including any remuneration, direct or indirect, overt or covert, in cash or in kind. This is a broad concept that, we believe, encompasses compensation/ remuneration obtained through an indirect financial arrangement. We further believe that an indirect relationship can occur in the ownership/investment situation as well as under a compensation arrangement. The term "indirect" appears specifically only in the definition of remuneration in section 1877(h)(1)(B), which applies

in the context of compensation arrangements. However, an ownership or investment interest as defined in section 1877(a)(2) may be through equity, debt, or *other means*. We believe that the term "other means" is broad enough to encompass an infinite variety of direct and indirect ownership or investment interests. As a result, we included the concept of an indirect ownership or investment interest in the proposed rule.

It was also our opinion that the Congress intended to cover all forms of financial relationships that may exist between a physician and a laboratory. Any other reading would allow physicians to easily circumvent the statute: they could hold ownership interests in entities furnishing clinical laboratory services by simply establishing and owning shares in holding companies or shell corporations that, in turn, own the laboratories.

The Congress has demonstrated its intention to cover situations involving indirect ownership and investment interests. As amended by OBRA '93, the language at the end of section 1877(a)(2)provides that "[a]n ownership or investment interest may be through equity, debt, or other means, and *includes* an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service." [Emphasis added.] This provision became effective January 1, 1995. However, we believe the amended provision demonstrates that, prior to OBRA '93, an ownership or investment held through "other means" could be interpreted to include indirect interests.

In addition, in proposing this amendment, the Committee on Ways and Means explained that "[t]he definition of financial relationship would be modified to include *explicitly* that an interest in an entity (i.e., holding company) that holds an investment or ownership interest in another entity is a financial relationship for purposes of the referral prohibition." [Emphasis added.] (H. Rep. No. 111, 103d Cong., 1st Sess. (1993).) In other words, we believe the intent of this amendment was to explicitly list a concept that was already implicitly included in the scope of the provision. The Conference Report for OBRA '93 reveals that the House Ways and Means provision was enacted without changes. (H. Rep. No. 213, 103d Cong., 1st Sess. (1993).) For these reasons, we decline to delete the term "indirect" and intend that it be considered in determining whether particular referrals are prohibited.

## 6. Group Practice

Under the proposed rule (§ 411.351), a group practice means a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association that meets the following conditions:

• Each physician who is a member of the group furnishes substantially the full range of patient care services that the physician routinely furnishes including medical care, consultation, diagnosis, and treatment through the joint use of shared office space, facilities, equipment and personnel.

• Substantially all of the patient care services of the physicians who are members of the group (that is, at least 85 percent of the aggregate services furnished by all physician members of the group practice) are furnished through the group and are billed in the name of the group and the amounts received are treated as receipts of the group. The group practice must attest in writing that it meets this 85 percent requirement.

• The practice expenses and income are distributed in accordance with methods previously determined by members of the group.

In the case of faculty practice plans associated with hospitals that have approved medical residency programs for which plan physicians perform specialty and professional services, both within and outside the faculty practice, this definition applies only to those services that are furnished to patients of the faculty practice plan.

"Group practice" as defined in section 1877(h)(4)(A), as it reads under OBRA '93, is discussed in section II.D.1.c.4. of this preamble.

## a. Threshold for "Substantially All"

*Comment:* A few commenters suggested that the threshold for what is "substantially all" of the services of physician members should be lowered from 85 percent to 75 percent because rural group practices would have difficulty in meeting the higher percentage. The same commenters noted that, if the threshold for group practices is not lowered, there should be a special threshold for rural group practices that may not be able to meet the 85 percent standard.

*Response:* The comments we received on the proposed rule have identified group practices that have partners, full and part-time physician employees, and physician contractors, who may also be either full- or part-time. All configurations of physicians must be