Furthermore, the commenter asked questions involving the following situations and suggested that it would be helpful to have specific examples presented in the final rule.

 Twenty-five percent of a clinical laboratory is owned by a professional corporation (P.C.) that, in turn, is owned by five physicians as equal shareholders. The P.C. also employs physicians who are not owners.

-Would a referral to the laboratory by a physician employed by the P.C. be prohibited?

Would referrals by any of the owners of the P.C. be prohibited?

- Two of the five physician-owners of the P.C. separately own the 25 percent interest in the laboratory rather than the entire P.C.
- —Would a referral to the laboratory by a physician employed by the P.C. be prohibited?
- Would a referral by one of the remaining three owners of the P.C. be prohibited?
- A company that is a general partner in a surgery center limited partnership also owns a clinical laboratory. The surgery center has as other limited partners a number of physicians. Can physicians who are limited partners refer patients to the company's laboratory?

Response: First, we want to state that it is not possible to provide specific answers to cover every possible variation of financial relationship. As noted elsewhere in this preamble, we receive a large volume of correspondence. To the extent that there is some uncertainty or confusion concerning a particular provision of the statute or regulation, we are ready to discuss the matter by telephone or in writing. We can, however, only provide our views about general questions; as mentioned previously, we cannot provide formal advisory opinions on specific circumstances.

In regard to the first set of questions, the commenter was concerned about indirect financial relationships with entities. As we explained in an earlier response, we believe that the language of the statute is intended to support indirect, as well as direct, financial relationships, as was specified in proposed section 411.351. In the preamble to the proposed rule, we stated that this would cover financial relationships with an organization related to an entity that furnishes clinical laboratory services. We gave as an example an interest in a parent or subsidiary corporation of the laboratory entity. The commenter's first question was whether the related entity concept

was limited to parent/subsidiary situations or whether brother/sister corporations would also be included.

Although the preamble gave the example of a parent or subsidiary relationship between entities, we believe that a physician can have an indirect financial relationship with a laboratory entity under any circumstances in which that physician owns some portion of an entity that has an ownership interest in the laboratory entity. This would be true regardless of whether the entities are related as parent/subsidiary or brother/sister corporations. In other words, these relationships are not the determining factor. For example, a physician's ownership interest might be in a nonlaboratory subsidiary of a parent laboratory corporation. If the physician has an ownership interest in the subsidiary without owning any portion of the parent laboratory, the physician will not be considered to have an ownership interest in the laboratory. The physician would have an ownership interest in the laboratory only if the nonlaboratory subsidiary had an ownership interest (for example, through stock or debt instruments) in the parent laboratory.

We believe the analysis is similar for brother/sister corporations or entities. Subsidiary entities that are related via a common parent may or may not have any ownership interest in each other. If a physician has an ownership interest in a subsidiary that, in turn, has an ownership interest in a brother laboratory, the physician could be regarded as having an indirect ownership interest in the laboratory. However, this would not be the case if the brother/sister corporations have no

ownership relationship.

The commenter also asked whether the relationship between entities depends upon stock ownership and, if so, what threshold percentage of ownership is required. The statute in section 1877(a)(2) defines as a financial relationship any ownership interest, regardless of the manner in which the interest is held or the amount of the interest. We believe this rule applies to all ownership interests, whether they are direct or indirect.

Our analysis of corporate relationships would also involve any compensation aspects of the relationships. As we said in the preamble to the proposed rule, any financial relationship between a physician and an organization related through ownership to a laboratory entity could be covered as an indirect financial relationship with the laboratory entity. In addition, even if a physician has an

ownership interest in a corporation that has no ownership interest in a laboratory entity, the physician may gain certain financial advantages from the relationship between the nonlaboratory entity and a laboratory that could constitute compensation to the physician from the laboratory. For example, if corporations file as one affiliated company, they may pool their gains and losses for tax purposes. As a result, a physician owner could receive some benefits from the affiliation.

The commenter recommended that we adopt an approach for related entities that is similar to that of the control group concept under the IRC. Generally, under section 414(b) of the IRC, employees of all corporations that are members of a controlled group of corporations (within the meaning of section 1563(a) of the IRC) are treated as employed by a single employer. Under 414(c) of the IRC, all employees of trades or businesses (whether or not incorporated) that are under common control are treated as employed by a single employer. Furthermore, under section 1563(a) of the IRC, a controlled group of corporations generally means the following:

 A parent-subsidiary controlled group is one in which one or more chains of corporations are connected through stock ownership with a common parent corporation.

 A brother-sister controlled group is one in which two or more corporations have five or fewer persons (individuals, estates, or trusts) owning certain levels of stock and controlling certain levels of voting power of all classes of stock entitled to vote.

Since we believe that the statutory language is very broad and encompasses both direct and indirect financial relationships, we cannot accept the commenter's suggestions to use the concept of a control group. Such a concept would narrow the scope of the provisions and would, thus, be inconsistent with the statute.

The commenter raised questions about several specific scenarios. In the first, a P.C. that is owned by five physicians owns 25 percent of a clinical laboratory. The P.C. also employs physicians. Referrals by physicianowners of the P.C. to the laboratory that is owned, in part, by the P.C. would be prohibited, unless an exception applies. Clearly, these five physicians have an ownership interest in the laboratory, even though it is indirectly held through their ownership of the P.C. We also believe that referrals by physicianemployees of the P.C. may be prohibited depending upon the following facts. If the P.C. is not a group practice and