employee-physicians are receiving remuneration from the owner physicians for their services as bona fide employees of the P.C., then, under section 1877(e)(2), the remuneration would not constitute a "compensation arrangement" if the (e)(2) requirements are met. The remuneration, therefore, would not subject the employeephysicians to the prohibition.

If the P.C. is a group practice, the employee physicians could be considered "members of the group." If so, the referrals of any one member of the group are imputed to the entire group. Because members who are owner physicians in the example may not be able to refer, then neither can the employees, unless an exception applies. If the P.C. is a group practice, the arrangement would need to be evaluated under the in-office ancillary services exception in section 1877(b)(2). That exception does not appear to dictate any particular ownership arrangements between group practice physicians and the laboratory in which the services are furnished. A group practice can take advantage of this exception, and members can refer to each other in the laboratory provided that the group meets the definition of a group practice under section 1877(h)(4). Under the exception in section 1877(b)(2), the services must be furnished by the referring physician or a group member or must be directly supervised by a group practice member. In addition, the services must be billed by the referring physician, the group practice, or an entity wholly owned by the group practice.

In the second scenario involving a P.C., the facts are different. Here two of the five physician-owners of the P.C. have an ownership interest in the laboratory, and this laboratory interest is separate from their ownership of the P.C. Obviously, referrals by those two physicians to the laboratory are prohibited, unless an exception applies. While additional facts surrounding this situation might lead to a different conclusion, it appears that referrals by the remaining three physician-owners of the P.C. and by physician-employees of the P.C. would probably not be prohibited. This is so because, in this case, the P.C. has no ownership interest in the laboratory and the other physicians have no ownership interest. Although the employees are perhaps indirectly compensated by the two owners, their referrals would not be prohibited if their employment arrangement meets the requirements in section 1877(e)(2). If the P.C. is a group practice, however, referrals of any member of a group practice (including

owners and employees of the practice) would be precluded, unless an exception applies, such as that in section 1877(b)(2). We stress that this conclusion is based on a minimal amount of information; the conclusion could change if it became apparent that any of the three physician owners or physician employees were receiving any income or compensation, directly or indirectly, from the laboratory. We also stress that sanctions could apply if this turns out to be a circumvention scheme.

Concerning the last question, our analysis of this situation indicates that referrals by limited partner physicians would not be prohibited as long as these physicians do not have a financial relationship with the laboratory or with the company that is a partner in the surgery center. That is, the physicians cannot have an ownership or investment interest in the laboratory itself or the company that owns the laboratory. In addition, there can be no compensation passing between the physicians and the laboratory or between the physicians and the company. When physicians and a company are partners in an enterprise such as a surgery center, their joint ownership does not necessarily mean that there is compensation or payment passing between them; they may simply both be investors. If the arrangement, however, is structured so that there is any compensation passing between the physicians and the company or the physicians and the laboratory, the physician's referrals to the laboratory would be prohibited, provided no exception applies.

Finally, we again remind the commenter that section 1877(g) sets forth sanctions that may be imposed if certain requirements of section 1877 are not met. For example, any physician who enters into an arrangement or scheme that the physician knows or should know has the principle purpose of ensuring referrals by the physician to a particular entity that, if they were made directly, would be in violation of the prohibition, would be subject to the sanctions imposed by section 1877(g).

3. Identical Ownership

Comment: One commenter suggested that group practices may own and operate a laboratory that has been set up as a separate entity. The commenter believed that this arrangement did not appear to be addressed in the proposed regulation. The commenter pointed out that often a group practice will own and operate a clinical laboratory as a separate entity for various financial, liability, and other legal reasons. This commenter believed that there does not appear to be any potential for abuse with these arrangements as long as the separate entity is wholly owned by the group practice or as long as there is identical overlap in ownership. Consequently, the commenter requested that the final rule clarify this point.

Response: As mentioned throughout this preamble, section 1877(a) prohibits a physician who has (or whose immediate family member has) a financial relationship with an entity furnishing clinical laboratory services from referring Medicare patients to that entity unless an exception applies. The statute does not contain a specific exception for wholly-owned entities. The commenter has not provided any evidence to convince us that any entity wholly owned by a group practice is free from program or patient abuse. Thus, we disagree with the conclusion reached by this commenter.

Concerning the commenter's reference to an identical overlap in ownership, we assume the commenter means that the same physicians who own the group practice also own the laboratory. As mentioned above, we do not believe that the Congress intended to except entities that are either wholly-owned or that have an identical overlap in ownership from the referral prohibition. Therefore, unless an exception applies, the physician or group practice owners would be prohibited from referring to a laboratory in which they have an ownership interest.

We believe that in many cases the inoffice ancillary services exception in section 1877(b)(2) would apply. For example, physicians in a group practice, as defined in section 1877(h)(4), can refer to a laboratory as long as the laboratory services are furnished personally by the referring physician or by another physician in the same group practice, or under the direct supervision of a physician in the same group practice; in a building that is used by the practice to furnish some or all of the group's laboratory services; and that are billed by the group practice or by an entity that is wholly owned by the group. We believe that this exception applies to any group practice that meets these requirements, regardless of who owns the laboratory, or the manner in which it is owned. Also, services furnished by a rural laboratory would be exempted, regardless of the circumstances of ownership.

4. Technical Change

Comment: One commenter recommended that the phrase "under that referral" at the end of proposed § 411.353(b) be changed to "under that