referral that is prohibited by paragraph (a)."

Response: We do not agree that this change is necessary, since "that referral" refers back to the earlier part of the sentence, which says "that is prohibited by paragraph (a) * * *."

5. Refunds

Comment: One commenter indicated that it is not unreasonable for an "entity that collects payment" to be required to make refunds in accordance with these regulations. The commenter believed, however, that the regulations provide no ability for the "entity that collects payment" to obtain the information needed to determine whether it is required to make a refund. The commenter suggested that the regulations either explicitly provide the means for the entity that collects payment to obtain the requisite referral information from the physician ordering the service or hold it harmless for refunds it does not make because it does not have the needed information.

Response: We do not agree with this comment. A laboratory is responsible for knowing with whom it has a financial relationship. Under section 1877(f) and our rule at § 411.361, laboratory entities are required, as specified by us, to provide us with information concerning their financial relationships, including ownership and compensation arrangements and including the names and unique identification numbers of all physicians with financial relationships or whose immediate relatives have financial relationships. Additionally, under the CLIA rules at §493.634, laboratories are required to provide and update ownership information.

E. General Exceptions to Referral Prohibitions Related to Ownership and Compensation

1. Physicians' Services

We proposed that the prohibition on referrals does not apply to physicians' services that are furnished personally by (or under the direct personal supervision of) another physician in the same group practice as the referring physician.

Comment: One commenter indicated that the proposed rule states that exempt physicians' services would have to be performed in the group practice's office. The commenter questioned whether the exception should be so limited. The commenter believed that if physicians' services, as that term is defined in the proposed rule, are performed in another entity furnishing clinical laboratory services for a group practice, the exception should apply as long as the physician performing the physicians' services and the referring physician are members of the same group practice. In other words, in the commenter's opinion, the physicians' services exception should apply regardless of whether the clinical laboratory is a group practice laboratory or a laboratory owned by another entity with which the group practice has a financial arrangement.

Response: We agree, in part, with this commenter. This exception applies to a limited number of services, that is, clinical laboratory services that are treated as physicians' services for Medicare purposes in the context of a group practice. We believe that the services can be performed anywhere and under any circumstances as long as they qualify as "physicians' services and are personally performed or personally supervised by another group practice member and do not otherwise result in a prohibited referral. Thus, physicians' services furnished by group practice physicians do not need to be furnished in group practice offices, provided they meet the other requirements in the statute.

2. In-Office Ancillary Services

Based on the provisions of OBRA '89, we explained in the proposed rule that the prohibition on referrals would not apply to in-office ancillary services if the following conditions are met:

• The services are furnished personally by one of the following:

+ The referring physician.

+ A physician who is a member of the same group practice as the referring physician.

+ Nonphysician employees of the referring physician or group practice who are personally supervised by the referring physician or by another physician in the group practice.

• The services are furnished in one of the following locations:

+ In a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of clinical laboratory services.

+ In the case of a referring physician who is a member of a group practice, in another building that is used by the group practice for centrally furnishing the group's clinical laboratory services.

• The services are billed by one of the following:

+ The physician performing or supervising the services.

+ The group practice of which the referring physician is a member.

+ An entity that is wholly owned by the physician or the physician's group practice.

(As discussed later in this preamble, OBRA '93 made significant changes to the in-office ancillary services exception (section 1877(b)(2).)

a. Referrals From Physicians Who Do Not Have a Financial Relationship With the Physician or Group Practice

Comment: One commenter suggested that a significant loophole is created in the proposal by exempting from the referral prohibition certain services provided by the referring physician, under his or her direction, or under the direction of others in the same group practice. The commenter suggested that, under this proposal, a group practice could establish a laboratory in its own office and accept referrals from outside physicians not associated with the group practice. The commenter believed that the acceptance of such referrals from physicians outside the group should result in that laboratory being considered an independent clinical laboratory owned by the physicians in the group. Therefore, the commenter believed that, under the terms of section 1877, the laboratory should no longer be permitted to accept referrals from the outside.

Some other commenters believed that the exemption for in-office ancillary services was adopted with the understanding that clinical laboratory services would be limited to the physicians' or group practices' own patients. According to these commenters, the regulations implementing the legislation should reflect this intent and specifically require that the exception apply only to physician office laboratories that do not accept referrals from physicians outside of the practice.

Another commenter believed that exempted group practice laboratories should meet the following two conditions:

First, the group practice laboratory should be fully financially integrated with the group practice, such that all group members and only group members share in laboratory expenses and income, and those expenses and income are distributed among group members in precisely the same manner and proportion as professional fees and expenses.

Second, the group practice laboratory should not be allowed to accept referrals of any tests from nongroup members.

This commenter believed that these restrictions would guarantee that the laboratory is in fact an extension of the group practice and not a distinct