to an entity as compensation for items or services other than clinical laboratory services if they are furnished at a price that is consistent with fair market value.

If the pathologist is considered a member of the group practice and makes referrals to the outside laboratory, whether the referrals would be prohibited depends upon the nature of the pathologist's relationship with the laboratory. The referrals might not be prohibited if the pathologist is the employee of the outside laboratory. In that situation, the payment the pathologist receives from the outside laboratory would not be "compensation" under section 1877(e)(2), which exempts any amount paid by an employer to a physician who has a bona fide employment relationship with the entity for the provision of services if certain standards

If the pathologist is independent but contracts with the outside laboratory, the compensation that flows from the outside laboratory to the pathologist could be excepted under section 1877(e)(3). This provision excepts remuneration from an entity under a personal service arrangement if certain standards are met.

If the pathologist owns the outside laboratory though, his or her referrals would be prohibited. That is because the pathologist would be referring to a laboratory in which he or she has an ownership interest (the section 1877(e) provisions except only compensation arrangements). Finally, if the pathologist is a member of the group practice, none of the group practice members can refer to the laboratory that is owned by the pathologist. That is because, in Section 431.351 of the proposed rule, we defined "referring physician" as a physician (or group practice) who makes a referral. Thus, any referral by one group practice member is imputed to the entire group practice.

7. Immediate Family

Under the proposed rule (§ 411.351) an "immediate family member" of a physician means husband or wife; natural or adoptive parent; child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

Comment: Two commenters recommended that we adopt what they believed to be a more manageable definition of immediate family member. They recommended eliminating, at the very least, the references to

grandparents, grandchildren, and assorted in-laws.

One of the two commenters recommended that the definition include "natural or adoptive parent, child or sibling" and exclude the remainder of the identified relatives. In this commenter's view, the definition of immediate family reaches beyond what is intended by the statute.

Response: As we stated in the proposed rule, our proposed definition is a longstanding definition used (in § 411.12) by the Medicare program to implement section 1862(a)(11), which excludes from Medicare coverage services furnished by an immediate relative. We also explained that, in our view, the definition encompasses the range of relatives who could be in a position to influence the pattern of a physician's referrals. These commenters simply stated their opinion that the definition is overreaching, without explaining why.

For these reasons, we are retaining the definition as proposed.

Comment: One commenter suggested that when an allowable clinical laboratory service is performed as part of a medical consultation by a family member of the referring physician, we should not prohibit that referral solely because the consulting physician is related to the referring physician.

Response: Under the definition of referral in section 1877(h)(5)(A), the request by a physician for an item or service covered under Part B, including the request by a physician for a consultation with another physician, and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician, constitutes a "referral" by a "referring physician." The first physician has, in sending his patient to the family member, made a referral under the statute.

If the family member performs or supervises the performance of the laboratory test, it is likely that the family member has either an ownership interest in the entity that performed the test and/or is compensated by the entity for supervising or performing the test. As a result, the first physician has referred a patient for laboratory tests to an entity with which his or her immediate family member has an ownership or compensation relationship. If no exceptions apply, this makes the referral a prohibited one. If the consultant family member merely orders the laboratory test from a laboratory in which neither he or she nor the first physician has a financial interest, the referral would not be prohibited.

We also point out that section 1877(h)(5)(C) provides that if a pathologist performs a laboratory test or supervises the performance of a test that is part of a consultation requested by another physician, the furnishing of the test by the pathologist or his or her request that the test be completed (under the pathologist's supervision) is not a referral. In other words, a self-referral by a pathologist as a result of a consultation does not constitute a referral for purposes of section 1877.

Comment: One commenter is a solo practitioner whose office is located in a building owned by herself and six other physicians, one of whom is her husband. In the building, there is an independent laboratory that is owned by the group practice to which her husband belongs. The laboratory was established by the physicians in the building for the practices in the building. The commenter did not think it is right that, because her husband has an ownership interest in the laboratory, her patients should not have access to it.

Response: Unless an exception applies, it appears, on the face of it, that the commenter is correct in stating that her referrals to the independent clinical laboratory would be prohibited. Her relationships with the laboratory appear to be as follows:

- She may have been an investor in the laboratory, because she was one of the "physicians in the building" who set the laboratory up "for the practices in the building."
- She is the spouse of a member of the group practice that now owns the laboratory.
- She is part owner of the building that houses not only the laboratory, but her solo practice and her husband's group practice as well.

It appears, therefore, that this physician, in addition to being an immediate family member of what may be a partial owner of the laboratory, may also be an investor in the laboratory herself (depending on the nature of her initial involvement in setting up the laboratory and any current financial interest) and may have a compensation arrangement with the laboratory based on rentals she presumably receives as a part owner of the building. We believe, however, that her family relationship generally controls to prohibit her referrals if her husband has an ownership or investment interest in the group practice or its laboratory or if he receives unexcepted forms of compensation from the group practice.

The physician's referrals would not be prohibited on the basis of her husband's ownership interest if the laboratory qualifies as a rural laboratory under