profit corporations. For example, a physician might own stock in a not-forprofit corporation or be a trustee of a charitable trust that operates a laboratory. The commenter suggested that this definition either be modified to contain an exception for nonabusive business entities or that the trust, foundation, and not-for-profit corporation criteria be deleted.

Response: We do not agree with this commenter. Under section 1877, unless an exception applies, any referral for clinical laboratory services is prohibited if the referring physician or a member of the physician's immediate family has a financial relationship with the entity to which the referral is made. This is so because the statute does not, in any way, limit the types of organizations covered by the referral prohibition as long as they provide clinical laboratory services. Therefore, our proposed definition of "entity" was meant to include all possible organizations and associations that provide laboratory testing. As was stated in the proposed rule, we believe that we need to define the term "entity" to ensure that the term is understood by all affected parties. Note, however, that if a trustee takes no compensation from and has no ownership interest in an entity, he or she would not have a financial relationship as defined in section 1877. Therefore, the physician would not be prohibited from referring Medicare patients to that entity. Finally, we are not aware of any situations in which a not-for-profit entity would issue stock.

4. Fair Market Value

Under the proposed rule (section 411.351), fair market value is defined to mean the value in arm's-length transactions, consistent with the general market value. With respect to rentals or leases, "fair market value" means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience of the lessor when the lessor is a potential source of patient referrals to the lessee. This definition is based on the definition in the statute. (OBRA '93 did not change the statutory definition.)

Comment: One commenter indicated that the statute makes it clear that lease and rental values may not be adjusted to reflect proximity to referral sources. The commenter was concerned about our statement in the preamble to the proposed rule at 57 FR 8599 that certain rental payments could be construed to

induce referrals, even if there is no explicit or implicit understanding regarding referrals. These arrangements would typically involve rental payments either substantially above or below the fair market value of the rental space. The commenter believed that there is still no adequate means to determine when an increase (or decrease) in value will be considered "substantial" and therefore viewed as suspect. The commenter agreed that an example of an abusive arrangement occurs when a physician rents space to a health care entity at a rate above what the market would ordinarily bear, and the entity agrees to the high rent because of an understanding that the physician will refer his or her patients to that entity.

The commenter pointed out that many factors influence what may be considered as "fair market value" in a normally functioning real estate market. For example, the principle that site rents vary inversely with increased travel time pervades the real estate industry. Thus, the commenter concluded, a facility that is convenient to places in which health care services are furnished, such as a laboratory adjacent to a medical building, will command higher rents than one across town.

The commenter suggested that the final rule should reflect some means of differentiating between rent and lease payments that have inherently greater values based on traditional economic factors and those that are "artificially" inflated.

Response: In using the term "substantially" in excess of or below fair market value, we were describing an example of how a rental or lease agreement could be an influence on referrals. Such an agreement could take many forms and incorporate a myriad of possible financial incentives depending on local factors that could influence the rental or lease price. We want to emphasize, however, that the definitions in the statute (section 1877(h)(3)) and regulations (§ 411.351) state that fair market value means that a rental or lease of property must be consistent with the value of the property for general commercial purposes and that a rental or lease of space may not be adjusted to reflect any additional value a lessee or lessor would attribute to the proximity or convenience of a potential source of referrals. Therefore, if the economic factor to which the commenter referred, that is, that site rents vary inversely with increased travel time, plays a part in determining the level of rent agreed to by a physician and a laboratory entity, the fair market value test set forth in the statue would

not be met. This would be the case even if the factor is a "traditional economic factor" that "pervades the real estate industry." In other words, if rent is inflated either artificially or because of its proximity to a referral source, the fair market standard would not be met and the exception would not apply.

5. Financial Relationship

In the proposed rule (section 411.351), we defined a "financial relationship" as either a direct or indirect relationship between a physician (or a member of a physician's immediate family) and an entity in which the physician or family member has—

(1) An ownership or investment interest that exists through equity, debt, or other similar means; or

(2) A compensation arrangement.

The OBRA '93 amendments added that, in addition to equity, debt, or other means, an ownership interest includes an interest in an entity that holds an ownership or investment interest in any entity providing clinical laboratory services. This expanded provision, however, is not applicable until January 1, 1995.

Comment: One commenter expressed strong support for the proposed policy that the prohibition would extend to physicians who are the previous owners of a laboratory, if they are paid by the new owners under an installment sales agreement that extends past January 1, 1992. The commenter indicated that such arrangements can easily be abused; that is, they raise the possibility that the previous owners would make referrals for the purpose of ensuring that the new owners continue to pay off their debt. Similarly, the commenter agreed with our statement that, if an organization related to the laboratory agrees to pay the laboratory's debt to the physician, a financial relationship is still created.

On the other hand, another commenter indicated that we should permit specific debt relationships if the following criterion is met: The debt interest is manifested by a written note that has a fixed repayment schedule unrelated in any fashion to the productivity of the debtor or any entity owned by the debtor, and the debtequity relationship of the debtor does not exceed 4 to 1.

Another commenter recommended that physicians who remain interested investors through a debt relationship in a laboratory that they once owned not be penalized. That is, the physicians should not be subsequently regarded as having a nonexempt financial relationship with that laboratory.