SSA '94 amended the OBRA '93 effective date provision so that the revised version of section 1877(e)(1) is retroactively effective to January 1, 1992. As a result, these terms are not reflected in this final rule.

## 2. Isolated Transactions

Under § 411.359(d) of the proposed rule, referrals by physicians involved in isolated financial transactions, such as the one-time sale of property, qualify for an exception if certain conditions are met and there is no other financial relationship between the entity and the physician for 1 year before and 1 year after the transaction.

*Comment:* Many commenters believed that the 1 year requirement creates substantial and unnecessary problems.

If a laboratory were to purchase assets from a physician on a one-time basis, it would not be able to accept future Medicare referrals from this physician if there were any previous relationship between the laboratory and the physician.

Response: We attempted in the proposed regulation to quantify and define an "isolated transaction" by adding the 1-year requirement. However, because commenters felt that this requirement creates substantial problems, we have decided to replace it with what we believe is a simpler and clearer standard. To define "isolated." we have eliminated the requirement that there can be no financial relationship between the parties for 1 year before the transaction, and we have shortened the period after the transaction. We have replaced this with the requirement that there can be no other unexcepted financial relationship between the parties for 6 months after the "isolated transaction." That is, if the two parties enter into a compensation arrangement within the 6-month period that qualifies for another exception, such as the employment or personal services exception, or if one of the parties qualifies for one of the ownership exceptions, the original transaction can still qualify as an "isolated" one.

We have also added a definition of "transaction" to make it clear that we regard an isolated transaction as one involving a single payment. If a financial relationship involves long term or installment payments (such as a mortgage), each payment constitutes a separate transaction, and would result in an ongoing financial relationship. (Individual payments between parties generally characterize a compensation arrangement. However, debt, as described in the statute in section 1877(a)(2), can constitute an ownership interest that continues to exist until the debt is paid off.)

3. Service Arrangements With Nonhospital Entities

Under proposed § 411.359(e), which reflects section 1877(e)(3) before it was amended by OBRA '93, referrals by a physician who has an arrangement to provide specific identifiable services to an entity other than a hospital would not be prohibited if the services are furnished—

• By the physician acting as the medical director or as a member of a medical advisory board of the entity in accordance with a Medicare requirement;

• As physicians' services to an individual receiving hospice care for which Medicare payment may only be made as hospice care; or

• As physicians' services to a nonprofit blood center.

The arrangement must satisfy certain requirements that also apply to employment and service arrangements with hospitals.

As discussed in section I.D.6.d. of this preamble, section 1877(e)(3) was amended by OBRA '93 and now provides that certain personal service arrangements with any entity will not be considered compensation arrangements for purposes of section 1877(a)(2)(B). This provision applies to remuneration paid by any entity to a physician, or to an immediate family member, for furnishing personal services. The exception applies if certain conditions are met. Finally, section 152(c) of SSA '94 amended section 13562(b)(2) of OBRA '93 (the effective date provision for OBRA '93) to create a new paragraph (D). This new effective date provision says that section 1877(e)(3), as amended by OBRA '93, is in effect beginning on January 1, 1992; however, until January 1, 1995, it does not apply to any arrangement that meets the requirements of section 1877(e)(2) or (e)(3) as they were in effect prior to the OBRA '93 amendments.

*Comment:* One commenter indicated that under the CLIA regulations (42 CFR part 493) laboratories must have physicians who act as laboratory directors, rather than medical directors. Thus, the commenter believed the regulations should be modified so that it is clear that a laboratory does not have a compensation arrangement if it pays a physician to act as the laboratory director of the entity.

*Response:* Under the revised provision in section 1877(e)(3), remuneration from an entity to a physician for the provision of the physician's personal services will not prohibit the physician from referring clinical laboratory services to the entity providing the following conditions are met:

• The arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement.

• The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity.

• The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

• The term of the arrangement is for at least 1 year.

• The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan described in section 1877(e)(3)(B), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

• The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

• The arrangement meets any other requirements the Secretary imposes by regulations as needed to protect against Medicare program or patient abuse.

*Comment:* One commenter indicated that there appear to be a number of relationships between clinical laboratories and physicians that are not specifically covered by proposed § 411.359 but would be protected by the fraud and abuse safe harbors. The commenter suggested that the final rule be expanded to specifically state that an arrangement would not violate the physician referral rule if it fits within a safe harbor under the fraud and abuse regulations.

*Response:* As mentioned in the preamble of the proposed rule and in the response to other comments, the anti-kickback and safe harbor provisions of the law and the section 1877 prohibition are intended to serve different purposes. The safe harbor provisions have been specifically designed to set forth those payment practices and business arrangements that will be protected from criminal prosecution and civil sanctions under the anti-kickback provisions of the statute. Conversely, section 1877 prohibits a physician's Medicare referrals for clinical laboratory services to entities with which the physician (or a family member) has a financial relationship when those referrals are not