hospital are furnished by the group under the arrangement.

+ The arrangement is set out in writing, specifies the services to be provided, and the compensation for the services under the agreement.

+ The compensation paid over the term of the agreement is consistent with fair market value and the compensation per unit of services is fixed in advance and 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 compensation provided is under an agreement that would be commercially reasonable even if no referrals were made to the entity.

+ The arrangement meets any other requirements imposed by the Secretary by regulation.

a. Joint Ventures Not Related to the Hospital Laboratory

Comment: One commenter suggested that the condition found in proposed § 411.357(b)(3)(ii) concerning 'ownership or investment in * hospital that * * * does not relate (directly or indirectly) to the furnishing of clinical laboratory services" could be construed as precluding a physician who has a financial interest in another hospital/physician joint venture that is unrelated to the clinical laboratory from referring to the hospital laboratory. This commenter recommended that the final rule clarify that physicians with financial interests in other hospitalphysician joint ventures will not be precluded from making referrals to the hospital laboratory.

Response: The proposed provision that the commenter asked us to clarify was based on the predecessor provision of section 1877(b)(4), which excepted a physician's financial relationship (ownership/investment interest or compensation arrangement) with a hospital if the relationship did not relate to furnishing clinical laboratory services. This provision was eliminated from the statute by section 13562 of OBRA '93, but was reinstated until January 1, 1995 by section 152(c) of SSA '94. The amended section 1877 also contains, in paragraph (e)(4), a new provision which excepts remuneration from a hospital to a physician if the remuneration does not relate to the provision of clinical laboratory services. Section 1877(e)(4) is retroactively effective beginning January 1, 1992, and remains in effect after January 1, 1995.

As for joint ventures, an exception for an ownership or investment interest held *with* a hospital may not be necessary. That is because section 1877(a)(2) defines a prohibited financial

relationship of a physician with an entity as an ownership or investment interest in the entity. In the case of a joint venture held with a hospital, if the physician has no ownership or investment interest in the hospital, a prohibition based on ownership would not apply at all. That is, even though a physician may own a venture with a hospital, as separate partners, that does not mean that the physician actually owns any part of the hospital.

To determine whether a physician has an ownership interest in a hospital, we must define what constitutes a "hospital" for purposes of section 1877. Under the Medicare statute, section 1861(e) defines a "hospital" as an institution, but we have never specifically defined what constitutes an "institution." Although section 1861 dictates what services and functions a "hospital" must provide to qualify as one, it does not appear to mandate any requirements relating to a hospital's corporate structure.

Hospitals often are structured in complex configurations as the result of tax laws and in response to a variety of business concerns. These configurations make defining a "hospital" almost impossible to do on a case-by-case basis. As a result, we are establishing a test that we believe will be relatively easy to apply. For purposes of section 1877, we are defining a "hospital" as any separate legally-organized operating entity plus any subsidiary, related, or other entities that perform services for the hospital's patients and for which the hospital bills. A "hospital" does not include entities that perform services for hospital patients "under arrangements" with the hospital. We believe these arrangements, by their very nature, involve situations in which hospitals contract with outside entities because they cannot or do not wish to provide the services themselves.

For example, a hospital might be a parent corporation that provides administrative services but that furnishes patient care primarily through a variety of subsidiaries such as a home health agency, a laboratory, or a radiology unit, each of which is independently incorporated. If the hospital bills Medicare for services provided by a subsidiary, then we regard the subsidiary as part of the hospital. A physician, as a result of this structure, could own a part of the hospital if he or she owns some of the remaining interest in the laboratory or other subsidiary, even if the physician does not own any of the parent corporation.

If a physician owns part of the hospital by virtue of owning some

portion of a separately incorporated subsidiary, then the physician's referrals to the hospital's laboratory could be prohibited (absent some exception). However, if the physician owns part of the hospital by virtue of owning some portion of a separate corporation that provides services other than clinical laboratory services, the exception in section 1877(b)(4) could apply until January 1, 1995. That is, the physician would have a financial relationship with the hospital (an ownership interest in the hospital) that does not relate to the provision of clinical laboratory services.

If, in contrast, a physician has an ownership interest in the hospital as a whole, we believe that this interest is indirectly related to the provision of clinical laboratory services. That is because, in most cases, a hospital's revenues will reflect the revenues earned by its clinical laboratory. It is for this reason that we included in proposed § 411.357(b)(3)(ii) the concept of ownership or investment interests that relate "directly or indirectly" to the furnishing of laboratory services.

Even if a physician has no ownership interest in the hospital (either in its operating entity or in a subsidiary), referrals to the hospital laboratory might still be prohibited, however, if the joint venture is structured so that there is some compensation passing between the hospital and the physician. If the hospital provides remuneration to the physician, that remuneration will result in prohibited referrals, unless an exception applies. Referrals would not be prohibited under section 1877(e)(4) and §411.357(g) of this final rule if the remuneration is unrelated to the provision of clinical laboratory services; for example, the hospital and the physician might jointly own a freestanding CAT scanning facility. Any remuneration that flows from the hospital to the physician would be excepted if the remuneration relates only to the CAT scanning operation. This result, however, will change when the prohibition on referrals is extended to other designated health services beginning on January 1, 1995.

Comment: There were several other comments relating to the exceptions that apply to financial relationships between physicians and hospitals. Some commenters maintained that there is a conflict between the exception set forth in section 1877(b)(4) and the proposed regulatory exceptions. The argument is that this section of the law establishes a general exception for financial relationships with a hospital if the relationship does not relate to the provision of clinical laboratory services