entitled "other arrangements with hospitals" and indicated that the provision is drafted so that this exception applies to compensation arrangements between a hospital and a physician (or family member) other than those arrangements described in §§ 411.359 (a) through (d). (These arrangements in paragraphs (a) through (d) include rental of office space, employment and services arrangements with hospitals, physician recruitment, and isolated transactions. To qualify for these exceptions, physicians and entities must meet a variety of conditions.) The commenter pointed out that, under section 1877(b)(4), the only condition is that a financial relationship cannot be related to the furnishing of clinical laboratory services.

The commenter has read the proposed rule to mean that the exception in § 411.359(g) applies only if the compensation arrangement is not one of the ones described under paragraphs (a) through (d). Thus, for example, a hospital may have one or a variety of arrangements with a physician who is performing outpatient surgery on a patient at the hospital. These arrangements could include the rental of office space, employment or service arrangements, physician recruitment arrangements, or isolated transactions. The commenter believed that if a physician had one or more of these arrangements but could not meet the conditions to qualify for an exception, the exception in §411.359(g) would automatically be foreclosed. That is, if the physician's financial arrangement was one already described in § 411.359 in paragraphs (a) through (d), then it could not be covered by paragraph (g), which applies only to financial arrangements other than those in paragraphs (a) through (d).

The commenter feared that the proposed rule could result in situations in which the hospital's laboratory would refuse to accept the physician's Medicare patient for laboratory work, with the result that the patient could not receive needed medical care at the hospital. The commenter questioned our authority to limit the statutory exception in section 1877(b)(4) and asked that we, at a minimum, add an exception for emergency laboratory work that would apply whenever, in the judgement of the physician, laboratory tests are needed quickly.

Another commenter recommended that the exception addressed in proposed § 411.359(g) be broadened to permit a direct or indirect financial relationship between a physician and a hospital or hospital affiliated organization or entity.

Response: In drafting § 411.359(g), we intended to cover any compensation arrangements that were not described in §§ 411.359 (a) through (d), including those that were the kinds of arrangements described in those provisions but that did not meet the conditions specified in them. We agree with the first commenter that the way we drafted § 411.359(g) is ambiguous and can cause confusion. As a result, we have made § 411.359(g) an independent exception, as it is in the statute.

We have also made several other changes to this provision to reflect amendments to the statute. As we have discussed in other responses, OBRA '93 eliminated section 1877(b)(4), which excepted any ownership/investment interest or compensation arrangement with a hospital that does not relate to the provision of laboratory services. The relationship could be between a physician and a hospital or an immediate family member and a hospital. SSA '94 reinstated section 1877(b)(4) until January 1, 1995. OBRA '93 also added paragraph (e)(4) to section 1877, retroactive to January 1, 1992. This new provision differs somewhat from paragraph (b)(4) in the sense that it retains only the compensation aspect of the exception. In addition, it applies only to remuneration from a hospital to a physician (not to a family member) if the remuneration does not relate to the furnishing of laboratory services.

The commenter also believed that we should provide an exception for referrals by physicians whenever, in the judgment of the referring physician, laboratory tests are needed quickly to treat a patient whose condition will worsen or be put at risk absent prompt laboratory results. We believe that section 1877 and this final regulation provide sufficient exceptions to ensure, in almost all cases, that patients should not be in the position of having their health threatened because of the general referral prohibition. In addition, the commenter's recommendation would give physicians total discretion that could be subject to abuse.

We do not agree with the suggestion that relates to broadening the exception in proposed § 411.359(g) so that it would apply to permit a direct or indirect financial relationship between a physician and a hospital affiliated organization or entity. The current authority in section 1877(e)(4) limits the exception to remuneration provided by a hospital, and not some other entity. We have interpreted the term "hospital" to include related or affiliated organizations or entities in situations in which the hospital bills for services

provided to hospital patients by the organizations or entities (except when the services are provided "under arrangements"). However, we do not believe that expanding the exception to other, non-hospital organizations or entities would necessarily be free of the risk of patient or program abuse.

Comment: One commenter asked that we explain what is meant by the phrase "does not relate to the furnishing of clinical laboratory services," as used in proposed § 411.357(b)(3)(ii) and § 411.359(g). The commenter wanted to know whether a physician who is not authorized to perform patient care services at a for-profit hospital but who has an ownership interest in the hospital is considered to have a financial relationship that is related to the provision of laboratory services. The physician receives dividends based on the business profits earned by the hospital. These dividends may in part depend on the provision of laboratory

Response: The commenter has asked about a physician with an ownership interest in a hospital. The commenter has apparently correctly perceived that, because the physician is not authorized to provide patient care services in the hospital, the exception in section 1877(d)(3) and in proposed § 411.357(b)(3)(i) would not apply.

For purposes of the exception in section 1877(b)(4) and proposed $\S411.357(b)(3)(ii)$, the commenter has asked whether the physician's ownership interest in the hospital relates (either directly or indirectly) to the furnishing of clinical laboratory services. We would consider the physician's ownership interest as related to the provision of clinical laboratory services. We base this conclusion on the fact that general ownership in a hospital includes an interest in the hospital laboratory. This exception could apply if the physician had an ownership interest in a subdivision of the hospital which did not provide clinical laboratory services. We would like to point out that, as the result of OBRA '93 (as amended by SSA '94), the exception in section 1877(b)(4)relating to ownership and investment interests is no longer in effect, beginning on January 1, 1995.

b. Ownership and Compensation

Comment: One commenter requested that the final rule clarify that a physician who meets the exception relating to an ownership or investment interest in § 411.357(b)(3) of the proposed rule not also be required to meet the exception relating to compensation arrangements in proposed