some laboratories may not properly conduct tests.

## 3. Laboratories Shared With Hospitals

*Comment:* One commenter requested that we create an exception for a shared laboratory facility owned by an organization or hospital that is exempt from taxation under section 501(c)(3) of the Internal Revenue Code if the laboratory is used in common under a written agreement with a group practice and if the group practice constitutes all or substantially all of the staff of the organization or hospital. The commenter stated that the requirement that the entity that owns the laboratory be tax exempt under section 501(c)(3) of the Internal Revenue Code provides significant protection against patient and program abuse. (To qualify for and maintain tax-exempt status, an organization must be a corporation, or a community chest, fund, or foundation, organized and operated exclusively for a community purpose such as for religious, charitable, scientific, public safety, literary, or educational purposes. No part of the net earnings of the organization can inure to the benefit of any private shareholder or other individual. Failure to meet these requirements, or failure to continuously maintain them, results in the denial or loss of tax-exempt status.)

The commenter believed that the conditions associated with tax-exempt status would prevent physicians from having an ownership interest in the laboratory from which they could receive financial benefits in the form of dividends or other distribution of earnings, as a result of their referrals. Consequently, there would be no incentive to order an excessive number of clinical laboratory tests. The commenter pointed out that payment for unreasonable or excessive compensation would also be prohibited by the restriction on private inurement.

Response: It is not clear from this comment exactly what the financial relationship is between the tax-exempt hospital/organization and the group practice physicians. We will first assume that it is the hospital or organization only that owns the laboratory and the physicians receive compensation from the hospital/ organization for providing staff services. This relationship will not prohibit referrals to the hospital's laboratory provided the compensation meets the requirements of one of the exceptions in section 1877. For example, section 1877(e)(2) (for bona fide employment relationships with an entity) or (e)(3) (for personal service arrangements with an entity) could apply. An additional

exception appears in section 1877(e)(7), which exempts certain group practice arrangements with a hospital when a group practice provides services for which the hospital bills.

If, on the other hand, the group practice physicians have an ownership interest in the laboratory, they would be referring to a laboratory in which they have a financial interest under section 1877(a)(2), even if they do not receive dividends or earnings. The physicians could refer to their own laboratory, provided they meet the in-office ancillary services exception in section 1877(b)(2) and § 411.355(b) of this regulation. If the laboratory is rural, then the ownership relationship would be exempt under section 1877(d)(2). If the physicians have an ownership interest in a tax-exempt hospital itself, their relationship could be exempt under several hospital-specific exceptions.

Because there are a number of exceptions available for situations involving compensation between a hospital or other organization and a physician, or for ownership in a hospital, we believe that a specific blanket exception for laboratory facilities associated with a tax-exempt organization or hospital would be unnecessary. Also, we are not convinced that such an exception would be free from any risk of patient or program abuse. For example, a nonprofit or tax-exempt organization can own a for-profit laboratory entity. Without further details and evidence, we would not grant such an exception.

Comment: One commenter indicated that an exception should be added for referrals to a laboratory facility that is shared by a hospital and a clinic. The commenter provided the following information. The clinic is a group practice. The shared laboratory is located on hospital premises, and the hospital owns the laboratory space. The clinic leases space from the hospital in an amount proportional to testing on the clinic's patients. Clinic staff manage the laboratory, and the clinic employs all the laboratory personnel. The clinic and hospital each own some of the laboratory equipment. As such, each entity essentially leases from the other entity the equipment needed to perform testing on its own patients. The laboratory is not a separate legal entity, but simply an arrangement that permits the clinic and hospital to work together. The parties entered into this arrangement in 1973 and it has been in effect since that time. Each party is responsible for billing and collecting fees related to laboratory services provided to its respective patients. The

agreement provides that the clinic and hospital would coordinate management, planning, budgeting, and accounting for the laboratory services. The commenter indicated that an exception should be allowed for referrals to a laboratory facility that is shared by a hospital and a clinic (group practice) where the parties divide expenses on a basis that reasonably approximates the costs associated with the tests performed for each party's patients and each party bills for and retains revenues associated with the testing of its own patients.

Response: The commenter has asked for a specific exception for arrangements in which a laboratory facility is shared by a hospital and a group practice clinic. The commenter has described an arrangement which involves a variety of ownership and compensation arrangements, each of which could cause the group practice physicians' referrals to be prohibited. However, as a result of the additional exceptions included in section 1877 by OBRA '93, we believe that most of the relationships described by the commenter could be excepted. As such, a separate exception would be unnecessary.

The commenter first describes several compensation arrangements between the hospital and the group practice. The group practice rents the laboratory space and some equipment from the hospital. (The laboratory is not a separate legal entity and is located on the hospital's premises, so we assume it is part of the hospital.) The hospital, in turn, rents some of the equipment from the group practice. These arrangements should not preclude the physicians' referrals if they meet the exceptions in section 1877(e)(1) (A) and (B), which exempt rental arrangements provided certain conditions are met.

The group practice also provides certain services to the hospital by managing the laboratory and employing the staff. We assume that the group practice is receiving some compensation, in some form, from the hospital for these services. This compensation would not trigger the referral prohibition if the arrangement meets the requirements in the bona fide employment exception in section 1877(e)(2) or qualifies for the exception for personal services arrangements in (e)(3). Alternatively, the relationship might be exempted under the exception in section 1877(e)(7) for certain group practice arrangements with a hospital under which the group provides clinical laboratory services which are billed by the hospital. In this case, the group practice appears to provide most, if not all, of the actual laboratory services while the hospital apparently bills for