Medicare. For other items, section 1877(h)(5)(B) covers a physician's request or establishment of a plan of care that includes furnishing clinical laboratory services. However, section 1877(a)(1)(A) specifically narrows the scope of section 1877 by describing the subset of referrals that are prohibited. Physicians were originally prohibited from making referrals to an entity for the purpose of providing clinical laboratory services. As of January 1, 1995, physicians are prohibited from making a much broader range of referrals to entities furnishing the other designated health services listed in section 1877(h)(6).

e. Hospitals and Group Practice Laboratory

Comment: One commenter believed that, if there is an "under arrangement" agreement between a hospital and a group practice for the group practice to provide laboratory services to hospital patients under section 1861(w)(1), it is the hospital and not the group practice physicians that is making a referral for the purposes of the section 1877 selfreferral proscription. The commenter pointed out that, for the most part, as recognized in the proposed regulation, a physician's request for a service is tantamount to a referral to a particular service provider. If services are being furnished to hospital inpatients and outpatients, however, the commenter indicated that it is the hospital's obligation to ensure that the services be performed and to direct that the services be performed by a particular party. Thus, in the commenter's opinion, it is the hospital that is making the referral to the group practice laboratory. Consequently, the commenter recommended clarification of the definition of "referral" and "referring physician" so that it is clear that a physician's ordering of clinical laboratory services for hospital patients does not constitute a "referral" within the meaning of section 1877.

Response: The commenter believed that we should revise the definitions of "referral" and "referring physician" to make it clear that, in the situation described in the comment, it is the hospital that makes a referral to a group practice laboratory and not the group practice physicians. We disagree with this interpretation. Every referral for clinical laboratory services must originate with a physician, and the general rule in section 1877(a)(1)(A)prohibits a *physician* from making a referral to an entity with which the physician (or an immediate family member) has a financial relationship. A "referral" need not even indicate a

specific laboratory. Section 1877(h) defines a "referral" as any request by a physician for an item or service or the establishment of a plan of care that includes the provision of laboratory services.

We do not believe that the Congress intended to allow physicians to circumvent the referral prohibition by imputing their referrals to an operating entity such as a clinic, hospital, or other institution. We believe that "referring physicians" and "referrals" involve only individual physicians or groups of physicians who send a Medicare patient or specimen to a laboratory for services.

Although, in our opinion, the general prohibition applies to the situation described by the commenter, there are exceptions within the statute that could apply to allow the group practice physicians to continue to refer.

Ťhe commenter has described a situation in which group practice physicians apparently provide patient care services to hospital patients. They refer hospital patients to the group practice's laboratory; the group practice laboratory provides laboratory services for the hospital under arrangements; and Medicare pays the hospital. The referring physicians in this case are referring to a laboratory that receives compensation from the hospital (the hospital buys laboratory services under arrangements). The hospital is also apparently compensating the group physicians for patient care services. The physicians, in addition, are likely to be receiving compensation from the group practice that owns the group practice laboratory and/or they have an ownership interest in the group practice and its laboratory.

We believe that the exception in section 1877(e)(7) could apply to allow referrals based on part of this scenario. This provision says that there is no "compensation arrangement" that would trigger the prohibition in section 1877, for arrangements between a hospital and a group practice under which the group practice provides laboratory services but the hospital bills for the services, if certain criteria are met. If the arrangement meets the criteria, the group practice should be able to refer to the hospital's laboratory without violating section 1877. That is because the underlying compensation passing between the hospital (which, in essence, is purchasing services from the group practice laboratory) and the group does not trigger the prohibition.

There is, however, a complicating factor in the commenter's scenario. That is, the group practice physicians are referring to their own group practice laboratory. It is likely that these physicians are receiving compensation from the group practice that owns the laboratory or that they own some portion of the group practice and the laboratory. The compensation or ownership interests involved here would require a separate exception in order to allow the group practice physicians to refer. The services could, for example, be excepted under the inoffice ancillary services exception in section 1877(b)(2), which allows a group practice to refer to its own laboratory if certain criteria are met.

In addition, the hospital may be separately compensating the group practice physicians for patient care services, compensation that is independent of the compensation the hospital pays the group to purchase laboratory services. The compensation from the hospital, however, could be excepted under section 1877(e)(2), if there is a bona fide employment relationship between the hospital and the physicians, or section 1877(e)(3) if the hospital is paying the physicians for personal services furnished to the hospital.

10. Referring Physician

We proposed, in § 411.351, to define a "referring physician" as "a physician (or group practice) who makes a referral as defined in this section."

Comment: One commenter believed that the definition of referral is not necessary because the statute is clear as written.

Response: We incorporated this definition in the rule to make the regulations as complete and clear as possible. Furthermore, this definition interprets the statutory term to include referrals made by an individual physician as well as referrals made by a group practice.

Comment: A commenter raised the issue of a physician who owns or manages a clinic but does not function as a physician by providing care to clinic patients. The physician also owns an interest in a clinical laboratory to which clinic patients or samples are sometimes referred. The commenter believed the physician-owner should not be considered a referring physician within the meaning of the regulation when he or she does not function as a physician. The commenter also believed that, if a clinic owner is only incidentally a physician, that professional degree should play no role in setting his or her legal obligations. In the commenter's view, to include physicians who are mere owners/ managers of clinics within the definition of referring physician would be arbitrary and prejudicial to them. The