meets the requirements in section 1877(b)(2). Under section 1877(b)(2), the services must be furnished by the referring physician or a group member or must be directly supervised by a group practice member. In addition, the services must be billed by the referring physician, the group practice, or an entity wholly owned by the group practice.

Comment: One other commenter indicated that, if an exception is provided for contracts for services provided "under arrangements" as described in section 1861(w), the language should be broad and not limited only to those circumstances in which the arrangement between the parties meets the safe harbor for personal services and management contracts provided for in the antikickback rules (42 CFR part 1001). According to this commenter, this limitation would pose several problems. First, the personal services and management contracts safe harbor would require that the aggregate amount of compensation be set in advance and not vary based on the volume or value of tests performed. This would mean that the parties would have to establish in advance a flat yearly fee for laboratory services. Even a fee schedule would not qualify for the safe harbor. A flat aggregate fee arrangement would be of concern to the hospital because it would place the group practice physicians at risk for the provision of clinical laboratory services that are the hospital's obligation. Under this arrangement, the physicians would have a financial incentive to order too few laboratory services for hospital inpatients and outpatients in order to make the arrangement as profitable as possible. To ensure that hospital patients receive optimum quality health care services, the hospital would not want the physicians to have a financial disincentive to order medically necessary laboratory services. The hospital would also be concerned that this contractual disincentive may have liability implications for the hospital in the event of a misdiagnosis of a hospitalized patient allegedly because the appropriate diagnostic testing was not ordered.

The safe harbor for personal services and management contracts also requires that contracts for less than full-time services be specific about the frequency and timing of the services being furnished. This commenter believed that a hospital in this situation must clearly expect that the group practice laboratory will furnish services for the hospital on an as needed basis when the patient and the patient's attending

physician require the laboratory service for appropriate diagnosis. Thus, the commenter concluded that this safe harbor criterion also could not be met.

Response: The commenter has described a situation in which group practice physicians both order and provide laboratory services to hospital inpatients and outpatients under an arrangement. We believe the commenter is correct in concluding that the section 1877 prohibition applies to both Part A inpatient hospital services as well as to Part B services.

The definition of "referral" found in section 1877(h)(5)(A) applies, by its terms, to items or services for which payment may be made under Part B of the program. Section 1877(h)(5)(A) is entitled "Physicians' Services," which are separate from inpatient hospital services and are always covered under Part B. Section 1877(h)(5)(B), on the other hand, covers "Other Items," and is not limited to Part B items and services. This provision states that, except for specific exceptions listed in (h)(5)(C), "the request or establishment of a plan of care by a physician" that includes clinical laboratory services constitutes a ''referral'' by a ''referring physician.' We believe this provision is difficult to decipher. Nonetheless, it appears to contemplate that physicians have made a "referral" in either a Part A or Part B context if they establish a plan of care for an individual that includes clinical laboratory services.
In the "inpatient hospital" context,

In the "inpatient hospital" context, we believe that most patients will receive clinical laboratory services as part of their "plan of care." We consider that anytime a physician orders anything, it is "pursuant to a plan of care" on the physician's part, even if not formally called that. In addition, we believe that the Congress fully intended to encompass Part A inpatient hospital services within the section 1877 referral prohibition. One of the designated health services that has been added to the prohibition effective January 1, 1995 (by section 1877(h)(6)(K)) is "inpatient and outpatient hospital services."

The commenter has asked about a specific exception for services furnished under arrangements. OBRA '93 amended section 1877 to establish such an exception in new paragraph (e)(7). This provision creates a limited exception for compensation that derives from an arrangement between a hospital and a group under which services are furnished by the group but are billed by the hospital. The provision specifies, in (e)(7)(A)(i) that, with respect to services furnished to an inpatient of a hospital, the arrangement is pursuant to the provision of inpatient hospital services

under section 1861(b)(3). Section 1861(b)(3) defines what constitutes "inpatient hospital services," and specifically includes certain services furnished to inpatients "under arrangements." Among other requirements in section 1877(e)(7), the arrangement must have begun before December 19, 1989, and have continued in effect without interruption since that date. Also, the compensation paid over the term of the agreement must be consistent with fair market value and the compensation *per unit* of services must be fixed in advance and not take into account the volume or value of referrals. Therefore, this exception does not present the "aggregate compensation" problem discussed in the comment. Also, there are no additional requirements for details about the frequency or timing of services furnished under a less than full-time service arrangement.

In response to the commenter's concern about the safe harbor for personal services and management contracts, we caution that the antikickback safe harbor regulations implement different provisions of the Act than are implemented by these regulations. Therefore, physicians and laboratory entities are obligated to consider the safe harbor requirements separately from the requirements of this rule.

4. Rental of Laboratory Equipment

Comment: One commenter stated that laboratories often rent a variety of equipment to physicians that they need in connection with their practices. For example, a physician may want to rent a blood analyzer in order to perform simple laboratory tests in his or her office. Since laboratories often have extra equipment they rent, the laboratory that the physician uses for his or her reference work will likely be the laboratory from which the physician rents equipment. Laboratories typically charge some rental fee for this equipment if the equipment is not an integral part of the laboratory services furnished. These arrangements could, however, be considered a compensation arrangement that could jeopardize the physician's referrals to the laboratory. The commenter believed that, if the equipment is leased at fair market value and meets other requirements comparable to those set out in the provision related to the lease of office space, there is little risk of patient or program abuse. Thus, this commenter recommended that an additional exception be created for referrals by a physician who has a compensation arrangement with a laboratory through