laboratory referrals only if a financial relationship exists between the referring physician (or an immediate family member) and the laboratory entity. In other words, the law does not prohibit a laboratory from accepting referrals from a physician who does not have a financial relationship with it. Therefore, in all situations, a group practice will be permitted to accept referrals for laboratory services from physicians in the community who do not have, or do not have an immediate family member who has, a financial relationship with the group practice or the laboratory.

## 8. Use of Diagnosis Code for Laboratory Billing

Comment: One commenter believed the government is being misled about the need for certain diagnostic testing. The commenter noted that self-referrals could be used by unscrupulous physicians as a means to generate income. The commenter believed a major check on this practice would be the requirement of an appropriate diagnosis code for each service billed. The commenter believed it should be the role of the Medicare carriers to monitor unnecessary testing and then to take appropriate actions so that no testing is paid for if the diagnosis code does not suggest medical need.

Response: Section 202(g) of the Medicare Catastrophic Coverage Act of 1988 (Public Law 100-360), enacted July 1, 1988, added paragraph (p) to section 1842 of the Act. Under the provisions of section 1842(p)(1), each bill or request for payment for physicians' services under Medicare Part B must include the appropriate diagnosis code "as established by the Secretary" for each item or service the Medicare beneficiary received. We fully explain the conditions and requirements of this provision in a final rule published on March 4, 1994 (59 FR 10290).

The conference report that accompanied Public Law 100-360 explained clearly the purpose of the requirement for physician diagnostic coding. After rejecting a Senate provision that would have required the use of diagnostic codes on all prescriptions, because they believed that the requirement would have been unduly burdensome on Medicare suppliers of services, the conferees agreed to require diagnostic coding for physicians' services under Part B. They explained their reasons for this requirement as follows: "This information would be available for immediate use for utilization review of physician services \* \* \*." (H.R. Conf. Rep. No. 661, 100th Cong., 2nd Sess.

191 (1988)) The new coding requirement does not apply to bills from laboratories, except for physician laboratory services, which are described in section 405.556.

Claims submitted directly to the Medicare carrier by a clinical laboratory that is not part of a physician's office are not subject to the above requirement. The Medicare carriers, however, review claims submitted for payment to ensure that, to the extent possible, only services that are reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member are approved for payment. We agree that it would be easier for a Medicare carrier to make a medical necessity determination if the claim contained an appropriate diagnosis coding. It is clear, however, that the Congress intended to limit diagnosis coding to physicians' services. Therefore, at this time, we are unable to accept the suggestion the commenter made.

## 9. Referrals That Are Not Abusive

Comment: One commenter indicated that it would appear that relationships between a practitioner and an entity would not pose a risk of patient or program abuse if the relationships do not result in a return to the practitioner of monies beyond those that would be received if the physician directly furnished such laboratory tests (or other Medicare outpatient services).

The commenter suggested that it would be helpful if an exception could be established for referrals, from a physician to an entity, that are medically necessary (that is, represent legitimate claims on the Medicare program) and are not motivated by direct or indirect financial benefits that exceed fair market value accruing to the physician.

**Response:** The commenter appears to argue that the prohibition should not apply to a referral that is made by a physician to an entity with which he or she has a financial relationship if the service being performed is determined to be medically necessary and the physician does not realize an unacceptable financial gain as a result of the laboratory referral. The financial gain could not be larger than the fair market value of what he or she would realize if the service was performed, for example, in his or her own office and would have qualified for the in-office ancillary services exception.

Section 1862(a)(1) states, in part, that, notwithstanding any other provision of title XVIII of the Act, no payment may be made under Part A or Part B of the Medicare program for any expenses

incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. In exercising their contractual responsibilities, Medicare carriers enforce this overriding coverage criterion through the use of claims screens, medical review, and other procedures. The commenter appears to believe that, because these carrier safeguards are in place, a "reasonable and necessary" exception could be established. The problem with this commenter's approach is twofold. First, section 1877 prohibits certain referrals to entities with which the referring physician or an immediate family member has a financial relationship regardless of whether the service furnished is found by a carrier to be medically necessary. Second, assessing whether a physician's referrals result in a financial gain from the relationship with a laboratory would be a very difficult and burdensome administrative process. Carriers process approximately 4 million claims for clinical laboratory services each year. It would be very costly to determine whether each claim called into question by certain referrals results in a cost benefit to the referring physician.

## 10. Contractor Implementation

Comment: One commenter, a Medicare contractor, indicated it had concerns with the administration of the prohibition on referrals along with the numerous exceptions that have been granted for specific services, certain ownership or investment interests, and certain compensation arrangements. The commenter anticipates that the monitoring of these various provisions will be complex and will greatly affect post-pay and systems areas.

Response: It is not clear, at this time, how significant a workload the provisions will create for carrier claims processing and fraud units. However, once this rule is published, the carriers will start performing compliance audits based on specified criteria. We do not expect that these audits will result in much increase in the carrier's workload. We do not believe that there will be any significant effect on either post-pay or systems areas.

## B. Scope of Regulations

Comment: One commenter indicated that the preamble section of the proposed rule explaining what the agency believes is the regulatory scope (57 FR 8593) should be omitted. The commenter contended that it imparts no specific guidance and defines no