Response: We agree with this commenter. As stated earlier, recent studies have concluded that there is a higher level of utilization of services when physicians refer patients to entities with which they have a financial relationship. As mentioned in the preamble to the proposed rule (57 FR 8589), a report from the Office of the Inspector General to the Congress established that at least 25 percent of the nearly 4500 independent clinical laboratories are owned in whole or in part by referring physicians. The same report found that Medicare patients of referring physicians who own or invest in independent clinical laboratories received 45 percent more clinical laboratory services than all Medicare patients. ("Financial Arrangements Between Physicians and Health Care Businesses," May 1989, page 18). A study published in "Medical Care" (Vol. 32, No. 2) in February 1994 found that a review of clinical laboratory practices in Florida lends support to the contentions of critics that physician joint ventures (health care businesses that physicians own, but where they do not practice or directly provide services) result in increased use of services and higher charges to consumers. Utilization, measured as the number of billable laboratory procedures per patient, is significantly higher in facilities owned by referring physicians. Although the study reported only negligible differences in charges per procedure (compared to nonphysicianowned facilities), it found that higher utilization rates resulted in significantly higher gross and net revenue per patient. Furthermore, the study found that differences in average production costs per patient in physician-owned and nonphysician-owned facilities were not significant. The net result is that physician joint ventures are far more profitable than comparable nonphysician joint ventures. The study results, which included laboratory services furnished to both private and publicly insured patients, corroborate previous evidence of higher use of laboratory procedures among Medicare and Medicaid patients treated by referring physician investors.

Many States have enacted or are considering regulations that would affect physician referrals to entities with which the physicians have financial relationships. For example, New Jersey implemented regulations that effectively prohibit physicians from referring patients to facilities they own. Physicians who do not comply with the regulations are subject to sanctions under the State's physicians practice law. Furthermore, in OBRA '93 the Congress has extended application of the prohibition on referrals to other types of health care services and health care entities.

6. Process for Amending Regulations

Comment: One commenter indicated that we should maintain an expedited process for amending the regulations and issuing clarifications. The commenter pointed out that, despite a careful review of the proposed regulations, it is not possible to identify all of the unintended consequences of applying the proposed regulations to particular laboratory arrangements. The commenter believed that unless we respond quickly to issue clarifications and correct such problems when identified, inappropriate regulations can disrupt the delivery of, and limit patient access to, quality clinical laboratory services.

Response: We understand and appreciate the commenter's desire to feel secure about the requirements of the law. We make all possible efforts to publish final rules as quickly as possible and to amend the regulations expeditiously if clarifications or changes are needed and can be accomplished through rulemaking. In addition, we keep our regional offices and the Medicare contractors informed through manual instructions of technical changes that can be made without rulemaking. The contractors, in turn, advise the physicians and laboratory entities in their service areas of such changes. In regard to inquiries about particular laboratory arrangements, our regulations do not provide for the issuance of formal advisory opinions of any kind pertaining to section 1877 or any other section of the law for which we are responsible. We receive a large volume of correspondence from the public, and we do respond to general questions about the contents of our regulations and manuals. We, however, do not have the authority and will not attempt to interpret the applicability of these physician self-referral provisions to situations posed in correspondence. Our advice must, of necessity, continue to be general.

7. Evolution of Group Practices

Comment: Before the enactment of section 1877 of the Act, the Medicare program did not have a statutory definition of "group practice," nor any detailed body of law developed through regulations or manual instructions to define or otherwise recognize a group practice as a provider entity. One commenter indicated that we should recognize the significance of this rulemaking to the development and evolution of group practices in this country.

The commenter expressed hope that regulations will recognize the diversity of business structures within the group practice field and accommodate nonabusive arrangements for the provision of clinical laboratory services based on the substance of the arrangements, not merely their form.

The commenter also indicated that we should be mindful of the significance of this rule to the competitive "playing field" in health care. It was stated that, as medical group practices evolve into larger and more full-service providers of a wide range of physician ancillary and other health care products and services, they are furnishing many items and services that have traditionally been furnished by inpatient institutions or independent suppliers. The commenter also expressed hope that nothing in the final rule will prohibit group practices from performing services for other physicians' patients or other providers assuming, of course, that the referring source does not have a prohibited financial arrangement with the group. The commenter applauded us for proposing a rule that does not force groups to choose between serving their own patients and those of otherwise unrelated physicians.

Response: In publishing these final regulations, it is not our intent to obstruct the efforts of an association of physicians to qualify as a group practice under the definition in section 1877(h)(4) and therefore qualify for the in-office ancillary services exception set forth in section 1877(b)(2) of the Act and described in §411.355(b). If a group of physicians meets the definition of a 'group practice'' under section 1877(h), it could also be eligible for the exception for physicians' services in section 1877(b)(1) and possibly the exception in section 1877(e)(7) for certain arrangements between a hospital and a group practice. Further, we believe that, to the extent possible, we have accommodated various group practice configurations given the statutory parameters.

The point made in the last sentence of the comment, as we understand it, endorses the adoption of a policy that would enable group practice laboratories to continue to perform laboratory tests for their own patients as well as to accept laboratory referrals from physicians in the community who do not have a financial relationship with the group practice. In the responses to various comments presented below, we have clarified that the provisions of section 1877 prohibit