business operating under the protection of the group practice.

On the other hand, another commenter recommended that we definitively state in the final rule that furnishing laboratory services on referral from outside sources will not disqualify a group practice laboratory from the in-office ancillary services exception if the laboratory meets all of the performance standards set forth in the definition of "group practice" in the statute and the proposed rule.

Response: There are two distinct issues that need to be addressed in responding to these comments. The inoffice ancillary services exception in section 1877(b)(2) provides that the prohibition on referrals will not apply to those services that are furnished personally by the referring physician, a physician in the same group practice as the referring physician, or by individuals who are (as amended by OBRA '93 and effective on January 1, 1992) directly supervised by the physician or another physician in the same group practice. This exception further contains location and billing criteria. It is our belief that this exception was provided for those clinical laboratory services that are performed as an adjunct to the patient care services of the attending physician. As such, the solo physician, the group practice, or an entity that is wholly owned by the physician or group practice must bill for the services.

On the other hand, the general prohibition on referrals applies only to referrals for clinical laboratory services made by a physician to an entity with which he or she or an immediate family member has a financial relationship. Section 1877 does not prohibit either a solo practitioner's laboratory or group practice laboratory from accepting referrals from outside physicians who do not have a financial relationship with the laboratory. When the solo practitioner or group practice, however, accepts referrals from sources outside of its office practice, the office laboratory is also acting as an independent laboratory because these services are not performed as an adjunct to the patient care services of the attending physician. As a result, the laboratory must have a billing number from the Medicare carrier and directly bill for the services that are performed on referral.

A physician or group practice cannot bill for the laboratory services furnished to the patients of another physician as if they were the physician's or group's own patients, under the physician's or group's provider number.

To summarize, we do not find anything in section 1877 that would

prohibit a physician or group practice office laboratory from accepting referrals from physicians who do not have a financial relationship with the laboratory, physician, or group. However, if such referrals are accepted, they cannot be billed by the physician or group practice. Rather, billing must be done under a billing number that is assigned by the Medicare carrier to the laboratory itself.

We would also like to point out that, if a member of the group is either performing or supervising the laboratory services, the quantity of outside tests could affect the group's ability to qualify as a "group practice" under the definition in section 1877(h)(4). Under (h)(4)(A)(ii), substantially all of the services of physician members (who now include any physicians during the time they work for the group) must be provided through the group and be billed in the name of the group (beginning January 1, 1995, these services must be billed under a billing number assigned to the group). If group practice members spend too much time supervising laboratory tests that are billed under the laboratory's separate number, the group practice could fail to meet the "substantially all" test.

## b. Independent Group Practice Laboratories

Comment: One commenter indicated that, while the point was not addressed in the proposed rule, we issued guidance to the carriers to deal with situations in which a group practice laboratory is also certified as an independent laboratory. The commenter wrote that we stated that the services must be billed differently depending on whether the test was referred for a patient of the group, or the test was referred from outside the group. The commenter suggested that it would be simpler for the groups and the government to have all services (physician, laboratory, and otherwise) billed to Medicare under one group billing number, regardless of the origin of the patient.

*Response:* We do not agree with this commenter. It has been an established Medicare policy that a laboratory a physician or group practice maintains solely for performing diagnostic tests for its own patients is not considered an "independent" laboratory. This means that the solo practicing physician or group practice can bill for in-office laboratory testing using the physician's or group practice's own billing number. Conversely, a physician providing clinical laboratory services to patients of other physicians is considered not to be furnishing "in-office ancillary" services and is, therefore, doing business as an independent laboratory. Since this policy has been in effect for over a decade, we believe that physicians or group practices that have been accepting referrals from outside physicians have already established that the laboratory is a separate entity for those tests and they are familiar with the billing rules.

Furthermore, as previously explained, section 1833(h)(5)(A) indicates that payment may be made only to the person or entity that performed or supervised the performance of the tests. There are several exceptions to this rule, including one in which, if a physician performed or supervised the performance of the test, payment may be made to another physician with whom he or she shares a practice. This would apply, for example, if the two members are members of a group practice. Taking these factors into consideration, we affirm that physicians and group practices can bill, under their provider number, for clinical laboratory services performed only for their own patients. If the physicians' or group practices' inoffice laboratory also provides reference work for patients of other physicians, that laboratory entity must bill for the services directly under its own number.

## c. Furnishing of Tests

Comment: One commenter indicated that the final regulations should provide further guidance regarding the scope of the term "furnished." For instance, the commenter understood that we take the position that consulting services designed to assist a physician in interpreting test results are not considered a part of the furnishing of the clinical laboratory test; rather, these services are considered to be physicians' services. The commenter further understood that we take this position even though interpretation services are included in the Medicare payment for the laboratory service and Medicare makes no other payment for the physician's interpretation services.

*Response:* At § 411.353(a) in the proposed rule, we defined clinical laboratory services for purposes of section 1877 as those services described in the CLIA regulations at § 439.2. Thus, a service would be covered under section 1877 as a "clinical laboratory service" only if the service is considered a clinical laboratory service under CLIA.

Some services may be billed as, for example, physician's services but they would still be subject to CLIA (and, as a result, to section 1877) if they fall within the scope of services described in § 493.2. This is so regardless of how they are billed. Under § 493.2, a laboratory means a facility for "the