The commenter pointed out that every time a patient is referred to a facility for chronic renal dialysis, clinical laboratory testing from categories 2 and 3 is required on an ongoing basis as part of the overall care of the patient. If the physician's plan of care for dialysis is deemed to include these tests for purposes of this rule, the commenter believed that the practical result would be to prohibit physicians from making referrals for tests to dialysis facilities in which they have an ownership interest.

A second commenter stated that the ESRD program includes in its composite rate payment methodology most items and services related to the treatment of patients with ESRD, including hematocrit and hemoglobin tests, clotting time tests, routine diagnostic tests, and routine diagnostic laboratory tests. Thus, the commenter pointed out, the determination of whether an item or service is included under the composite rate payment is presumptive and in no way depends on the frequency with which a dialysis patient requires the item or service. The commenter recommended that the final rule, or the preamble to the final rule, explicitly exclude clinical laboratory referrals covered by ESRD from its application.

Response: Section 1877(h)(5)(B) says that "the request or establishment of a plan of care by a physician which includes the provision of [clinical laboratory services constitutes a ''referral'' by a ''referring physician.'' The commenter has pointed out that this provision, carried over into the proposed rule, is ambiguous and unclear. The statute could mean (1) that there is a referral when a physician establishes a plan of care or requests that one be established that includes laboratory services or (2) that a request by a physician that includes the provision of laboratory services or the establishment of a plan of care by a physician that includes the provision of laboratory services constitutes a referral. Because the comments reveal that this provision has caused confusion, we have decided to adopt the latter interpretation and have incorporated it into the regulation.

We also agree that it is not clear what technically constitutes a "plan of care." We believe that any time a physician orders any item, service, or treatment for a patient, that order is pursuant to a plan of care. If a plan of care entails laboratory testing and the facility or other individual implementing the plan orders those tests from a laboratory, the physician who established the plan of care is considered to have made the laboratory referral. In addition, as we mentioned in a previous response, the

prohibition could also apply if the individual implementing some or all of the plan of care is a consulting physician. We agree, however, that, under certain circumstances, this may cause problems when those laboratory tests are included in the ESRD composite rate. Thus, as we discuss below, we are including those laboratory tests that are paid under the ESRD composite rate as part of a new exception. We agree that the application of the composite rate constitutes a barrier to either Medicare program or patient abuse because the Medicare program will pay only a set amount to the facilities irrespective of the number and frequency of laboratory tests that are ordered.

c. Consultation Referrals

Comment: A few commenters believed that it was unnecessary for us to include in the preamble the discussion about consultations (57 FR 8595) and the responsibility of a consulting physician to not engage in a cross-referral arrangement. They believed there is no corresponding statutory or regulatory provision and that, except for a small number of truly "bad apples" practicing medicine, physicians have not and will not engage in the complicated and tortuous process of directing referrals.

One commenter was concerned that the proposed rule suggests that physicians who refer to consultants have some obligation to tie the consultant's hands when it comes to which clinical laboratories the consultant can use. The commenter believed such an obligation runs afoul of the principle of medical ethics that requires a physician to refer patients to the entity that furnishes the most efficacious service, regardless of other considerations. The commenter indicated that, in a managed care setting, it may be impossible for the attending physician to even know who the consulting physician is, much less be in a position to dictate which laboratory is selected. In sum, this commenter believed that it will be difficult in practice for physicians to determine where the prohibition ends.

Response: We do not agree with these commenters. In response to the first comment, the discussion in the proposed rule was based on the statute at section 1877(g)(4). This provision says that "any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity

which, if the physician directly made referrals to such entity, would be in violation of [section 1877], shall be subject to a civil money penalty * * *.

Because the provision applies to physicians who make referrals and to 'other entities," we believe that it can apply to consulting physicians who help a physician indirectly make prohibited referrals. In the preamble of the proposed rule (57 FR 8595) we stated that, if a consulting physician deems it necessary to order clinical laboratory services, those services may not be ordered from a laboratory in which the referring physician has a financial interest. We included this explanation to give the reader an example of the kinds of referrals that are prohibited under the statutory definition of "referral." Under section 1877(h)(5)(A), a request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by or performed under the supervision of that other physician) constitutes a referral. Thus, it is necessary for the consulting physician to be aware of any financial relationships the referring physician may have with a laboratory, in order for the referral not to be prohibited. Finally, the consulting physician is also obligated not to refer laboratory testing to an entity with which he or she has a financial relationship, unless an exception applies.

Concerning services furnished in a managed care setting, section 1877(b)(3) provides a general exception for services provided to patients enrolled in the prepaid health plans listed in that provision and in the regulations at § 411.355(c).

d. Statutory Authority

Comment: One commenter noted that the statutory definition of referral encompasses requests for any item or service for which payment may be made under Medicare Part B, but the prohibition contained in the statute is aimed at referrals for clinical laboratory services and not other referrals. Thus, in the commenter's view, the statute makes the rule somewhat confusing. That is, the behavior that the statute seeks to restrict, referrals for clinical laboratory services, is narrower in scope than the behavior of "referring" itself. Therefore, the commenter suggested that the final rule clarify that the prohibited behavior is related to clinical laboratory services.

Response: We agree that the definition of "referral" under the statute at section 1877(h)(5) is broad. In section 1877(h)(5)(A), for physicians' services, it covers a physician's request for any item or service covered under Part B of