+ To order or communicate the results of tests or procedures for the entity.

This provision also excepts payments made by an insurer or self-insured plan to a physician for the physician's claims under certain circumstances.

Thus, we believe that, when a laboratory writes off a debt to essentially correct the records between the parties, the exception described above would apply. However, if a laboratory has a continual pattern of disposing of the debt of its referring physicians in this manner, we might scrutinize the situation under the circumvention scheme provision (section 1877(g)(4).) Negotiations between parties about the correct amount of money owed for services delivered, resulting in a balancing of accounts, would also qualify under this exception, as well as the exchange of certain laboratory supplies, telecommunications equipment, and courier services.

One commenter mentioned that "other benefits" exchanged between a physician and a laboratory could be educational or consultation services. Section 1877(e)(3) provides that a physician who has a personal services arrangement (or an immediate family member with a personal services arrangement) with a laboratory entity (for example, to furnish consultations or educational services) may refer patients to that entity if certain conditions are met. Also, section 1877(e)(8)(B) allows a physician to make payments to any entity (including a laboratory) for items and services, other than clinical laboratory services, if the purchase is consistent with fair market value.

Because of these facts, we are retaining the proposed definition of remuneration but are explaining that certain day-to-day business transactions as listed in the statute are not included in this definition.

c. Payments

Comment: One commenter objected to including the term "payment" in the definition of remuneration. This commenter pointed out that payments frequently occur between laboratories and physicians and, in many instances, these payments do not create incentives for physicians to order increased laboratory testing. For example, in the commenter's opinion, the following situations do not create incentives for physicians to increase their laboratory referrals.

• The laboratory *pays* a physician who furnishes interpretation or consultation services such as Pap test interpretation, tissue pathology

consultations, or EKG holter monitor readings.

- A laboratory *pays* a physician a refund as a result of an overpayment or to settle a disputed claim.
- A laboratory that maintains a selfinsured group medical plan for its employees *pays* a physician who furnished services to a laboratory employee.
- A laboratory *pays* a physician to be on call to come to its blood-drawing station in case of an emergency, as required by State law.
- A physician *pays* the laboratory for the provision of a nonlaboratory service that it furnishes or that is furnished by a subsidiary or related corporation, for example, billing, management or consultation services, or the provision of some other medical product or service.

Response: As stated above in response to a similar comment, section 1877(h)(1)(B) provides that, for purposes of determining whether a compensation arrangement exists, the term remuneration includes "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." One of the definitions found in the American Heritage Dictionary of the English Language for "remuneration" is "payment." Therefore, we believe we are correct in concluding that, in general, payments between a laboratory and a physician are a form of remuneration. Arrangements involving remuneration between these parties can, in turn, be characterized as "compensation arrangements." Most, if not all, of the examples provided by the commenter could now fall within specific statutory exceptions. Examples one, three, and four could be excepted under section 1877(e)(3), which excepts certain situations in which an entity pays a physician under a personal service arrangement. The second example could be remuneration that is excepted from the definition of a "compensation arrangement" under section 1877(h)(1)(A) and (C), and the fifth example could be excepted under section 1877(e)(8)(B), which excepts payments by a physician to an entity in exchange for items or services other than clinical laboratory services.

We realize that many legitimate transactions occur between laboratories and physicians. We believe that most of these will qualify for the exceptions listed above. But, in the case of continuing arrangements that provide for payment between laboratories and physicians that do not qualify for the exceptions, the prohibition applies.

D. Prohibition on Certain Referrals by Physicians and Limitations on Billing

1. Medicare Only

Comment: One commenter indicated that the final regulation concerning the prohibition should include a statement that a physician's referrals for non-Medicare patients to receive clinical laboratory services, which are not reimbursable under Medicare, are not affected by section 1877 or this rule.

Another commenter requested that the final rule confirm that the statute and the proposed rule do not apply to State Medicaid programs.

Response: In the preamble to the proposed rule (57 FR 8595), we stated that the general prohibition on referrals applies only to referrals for clinical laboratory services that would otherwise be covered by the Medicare program. Therefore, referrals for clinical laboratory services to be furnished to a physician's non-Medicare patients are not affected by section 1877. This concept is reflected in section 411.353(a) of this rule. As a result of section 13624 of OBRA '93, however, section 1877 will have an effect on the Medicaid program beginning with referrals made on or after December 31, 1994. (We plan to address this matter in a separate proposed rule.)

2. Related Parties

Comment: The preamble to the proposed rule (57 FR 8596) states that a financial relationship between a physician and an organization related to an entity that furnishes clinical laboratory services (for example, a parent or subsidiary corporation of the laboratory entity) is to be considered an indirect financial relationship with the entity.

One commenter believed that this concept needs clarification and that it would be helpful to have some "bright line" rules for what constitutes a related entity. The commenter asked several sets of questions, which, as we understand them, are as follows:

- Is the related entity concept limited to a parent/subsidiary model or will brother/sister corporations be included?
- Is the relationship between the entities to be defined in terms of a stock ownership requirement and, if so, will a threshold percentage of ownership be required?

In this regard, the commenter suggested that we may want to review the control group concepts set out in sections 414(b) and 414(c) of the Internal Revenue Code of 1986 (IRC) and to consider adopting a similar approach.