commenter added that such a physician should be compared to nonphysician clinic owners or managers who are not covered by the statute or its implementing regulations. Clearly, according to the commenter, clinic owners or managers with medical degrees should have the same legal status as nonphysician owners or managers. Thus, the commenter recommended that the final regulation, or its preamble, explicitly exclude from the definition of referring physician, physician-owners who neither practice medicine nor make direct referrals to clinical laboratories.

Response: Section 1877 prohibits referrals by "physicians" and does not qualify "physicians" to exempt any subset of these individuals. Since section 1877 does not define who is a physician for purposes of that section, the usual Medicare definition of that term applies. "Physician" is defined in the statute, at section 1861(r), as a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action (including osteopathic practitioners within the scope of their practice as defined by State law). The definition also includes a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, and a chiropractor. These additional individuals qualify as "physicians" only when they are performing within the scope of their license or providing items and services that they are legally authorized to perform within their specialty. The Medicare regulations define "physicians' services" at 410.20 as those furnished by one of these individuals who is legally authorized to practice by the State and "who is acting within the scope of his or her license. Arguably then, a physician who owns or manages a clinic but does not provide any of the items or services authorized within the scope of his or her license would not be a "physician" for purposes of section 1877. However, if such an individual refers clinic patients to a particular laboratory or attempts to influence a clinic physician to make such referrals, that individual's status changes. That is, he or she has become involved in the care of particular patients and is therefore acting in the role of a physician. As a result, the provisions of section 1877 (including the provision prohibiting circumvention schemes and indirect referrals) would apply.

## 11. Remuneration

We proposed, in section 411.351, to define "remuneration" as "any

payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in kind."

## a. Discounts

Comment: Some commenters supported the concept of including discounts in the definition of remuneration. They indicated that it is not unusual for a physician with substantial Medicare business to obtain a larger discount than a physician who has no Medicare business. Discounts, in the view of these commenters, can therefore influence a physician to use a particular laboratory and, in an extreme case, the prospect of a deeper discount may even induce a physician to order unnecessary tests.

One commenter offered the opinion that the intent of the legislation is clear from the definition of "compensation arrangement," which is defined to include all forms of remuneration, direct or indirect, overt or covert, in cash or in kind.

Another commenter indicated that the existence of a discount arrangement has a strong potential to result in excessive laboratory testing, which contributes to the distressing rise in health care costs in this country.

Some commenters objected to including "discounts" in the definition of remuneration because they believed the term "discounts" is vague, overbroad, and impossible to define. In their view, the definition would be fraught with unintended adverse consequences. One commenter believed that a compensation arrangement, for the purpose of section 1877, should be created only whenever the following situation occurs: (1) Some remuneration passes from a laboratory to a physician; and (2) the prospect of remuneration gives the physician an incentive to order increased testing.

One commenter indicated that, to a certain extent, physicians receive a lower price than other payers because of the legitimate cost savings associated with physician billing.

Two commenters stated that there is nothing inherently abusive about discounts. One of the commenters believed that what gives the physician an incentive to increase his or her utilization of testing is not the discount; it is his or her ability to mark up the testing and thereby derive a profit from the transaction. The other commenter suggested that discounts be permitted if the laboratory can meet the following conditions:

• The discount is not tied to the referral of Medicare specimens to the laboratory.

- The discount is related to verifiable cost differences in handling specimens that satisfy the conditions for the discount, including cost differences due to such factors as economies of scale, lower billing and collection costs, prompt and regular payment, or reduced bad debt cost.
- The discount is available to anyone who can satisfy the requirements for the discount, for example, type of test or other objective requirement; and
- The discount is not provided to any referring physician. (We assume by this that the commenter meant that discounts a laboratory entity would make to providers of services, such as hospitals, would be permissible under these guidelines.)

Response: As discussed earlier, section 1877(e)(8)(A), as added by OBRA '93, provides that a physician may make payments to a clinical laboratory in exchange for furnishing clinical laboratory services and continue to refer Medicare patients to that laboratory. There is no requirement that the payments meet any particular pricing standards. However, when a laboratory provides a physician with a discount, it may in some cases be providing that physician with a benefit (that is, remuneration) that is separate from the payment that the physician has made to the laboratory to purchase laboratory services. Since we are not interpreting the OBRA '93 provisions in this rule, but merely reiterating them, we have not yet taken a position on how this new provision will affect discounts. We will interpret section 1877(e)(8)(A)and how it applies to discounts in the context of the proposed rule covering all of the designated health services.

In regard to discounts for items and services other than clinical laboratory services, a physician may purchase other things from a clinical laboratory besides clinical laboratory services. Section 1877(e)(8)(B) allows a physician to purchase from any entity items and services, other than laboratory services, as long as they are purchased at fair market value. Section 1877(h)(3) defines fair market value as the value in arm'slength transactions, consistent with the general market value, which would not include discounts. In light of section 1877(e)(8)(B), we are keeping "discounts" in the definition of "remuneration." As a result, discounts would remain "compensation arrangements" for discounts on items or services such as supplies or personnel or consulting services purchased by a physician from a clinical laboratory or other entity.

Comment: One commenter indicated that providing a discount to physicians