reimburse the laboratory for those services before marking them up to patients. The commenter did not believe that those payments should constitute a compensation arrangement.

*Response:* As set forth in OBRA '93, section 1877(e)(8)(A) of the Act provides a compensation-related exception for physicians who pay a laboratory in exchange for the provision of clinical laboratory services (see section 411.357(i)(1)).

The commenter has made the point that physicians routinely reimburse laboratories for services and then mark them up to patients. Under section 1833(h)(5)(A), Medicare payment for a clinical diagnostic laboratory test may be made only to the person or entity that performed or supervised the performance of the test. (This rule is subject to certain exceptions involving services furnished or supervised by a physician when payment is made to another physician in the same group practice, services performed by a laboratory at the request of another laboratory, and tests performed under arrangements made by a hospital.) As a result, physicians should generally not be able to pay a laboratory in exchange for Medicare covered laboratory services, and then mark them up to patients.

*Comment:* One commenter noted that many laboratories are part of large, diversified corporations (which themselves may be related to other large, diversified corporations) that provide a number of different services to physicians. These services may include pharmaceutical, billing, and waste transport services. The commenter believed that, so long as these services are provided at fair market value, there is no reason that an entity should not provide these services to physicians and also accept their Medicare referrals.

*Response:* As mentioned previously, if a physician is paying fair market value to the supplier entity for whatever nonlaboratory services he or she is purchasing, referrals by the physician to the laboratory should not be prohibited. However, the arrangement must meet the conditions found in new § 411.357(i).

*Comment:* One commenter indicated that the regulations should be clarified to expressly prohibit any arrangement under which the referring physician bills patients for clinical laboratory or anatomic pathology services that are not personally performed or supervised by the billing physician or the group practice. In particular, the commenter suggested that the prohibition should apply to arrangements under which the referring physician requires the

pathologist or independent laboratory to bill the referring physician, rather than the patient or third party payer, for any services provided by the pathologist or independent laboratory on referral by the physician. The commenter pointed out that, at the present time, the Medicare payment rules prohibit a physician from billing for certain clinical diagnostic laboratory tests performed by an independent laboratory for Medicare patients (section 1833(h)(5)(A) but, the commenter maintained, this payment prohibition does not apply to anatomic pathology services or to clinical laboratory services performed for non-Medicare patients. Thus, the commenter concluded that the referring physician would not be prohibited from marking up the costs of anatomical tests to Medicare and for clinical laboratory and anatomical testing billed to other third party payers.

The commenter believed that an arrangement under which the referring physician charges payers for the services of a separate laboratory constitutes a compensation arrangement within the meaning of the law. The commenter added that "compensation arrangement" is defined as any arrangement "involving any remuneration." Further, the term "remuneration" is defined broadly to include direct or indirect, overt or covert, and in-cash or in-kind arrangements. The commenter believed, therefore, that an arrangement under which the referring physician can receive payment for services not personally performed or supervised by himself or herself, including payment for services for non-Medicare patients, should be found to be a compensation arrangement within the broad language of the law.

Specifically, the commenter recommended that the final regulation make clear that the definition of "compensation arrangement" encompasses any arrangement under which a referring physician bills and collects for laboratory services that are not personally performed or supervised by the physician.

*Response:* This commenter raised several issues: first, whether anatomical pathology services are diagnostic laboratory tests and, thus, subject to the billing requirements of section 1833(h)(5)(A); second, whether the billing requirements of that section can be applied to clinical diagnostic laboratory tests performed for non-Medicare patients; and third, whether the definitions of compensation and remuneration at section 1877(h)(1) can be broadly interpreted to include payments made to the physician for any laboratory services he or she did not personally perform or supervise, including payment for services for non-Medicare patients. We will address each of these issues in order.

Under Medicare, the term "medical and other health services" includes, under section 1861(s)(3), the broad category of "diagnostic laboratory tests." Under section 1861(s)(16), such diagnostic laboratory tests include only those diagnostic tests performed in a laboratory that meets CLIA requirements. Anatomical pathology services are tests involving tissue examination, such as that done during surgery. We believe that any anatomical pathology tests would be diagnostic in nature and would have to be performed in a laboratory that meets CLIA requirements. As such, the tests fall squarely within the category of "diagnostic laboratory tests" and would therefore be subject to the payment rules in section 1833(h)(5)(A).

Under section 1833(h)(5)(A), payments for clinical diagnostic laboratory tests are subject to mandatory assignment. That is, with certain narrow exceptions, payment may be made only to the person or entity that performed or supervised the performance of the test. Further, under section 1842(b)(6), a carrier generally may pay assigned benefits only to the physician or other supplier that furnished the service. Thus, unless physicians are billing Medicare within the conditions found in these provisions of the law, they are billing in error.

In regard to the second issue, the language of section 1833(h)(5)(A) applies specifically to services for which payment may be made under Medicare Part B. Therefore, we agree with the commenter that the billing requirements found in the Medicare statute do not extend to non-Medicare patients.

In regard to the third issue, under section 1877(e)(8)(A), payments by a physician to a laboratory for clinical laboratory services do not constitute compensation that triggers the referral prohibition.

## 3. Entity

In the proposed rule (§ 411.351), we defined "entity" as a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association.

*Comment:* One commenter indicated that the statute does not define "entity" and the definition in the proposed regulations could prohibit certain nonabusive arrangements because it covers trusts, foundations, and not-for-