

clinical laboratory services for physician referral purposes.

Comment: One commenter suggested that it would be helpful to define further what type of anatomical laboratory services are covered by the statute and which specific tests we consider to be noninvasive and not subject to the prohibition on referrals.

Response: We agree with this commenter. As mentioned in the preamble to the proposed rule (57 FR 8595), anatomical laboratory services are subject to the prohibition on physician referrals. Anatomical laboratory services (and anatomical pathology services) involve the examination of tissue, often tissue removed during surgery. As such, it appears to us that anatomical laboratory services are always invasive (that is, they involve the examination of materials derived from the human body, as described in 42 CFR 493.2).

Therefore, we believe that these tests would always be subject to CLIA and section 1877. Consequently, any physician who refers patients for these kinds of tests to a laboratory with which he or she (or a family member) has a financial relationship could be in violation of section 1877. In such a case, any of the many exceptions in section 1877 might exempt that physician's referral from the prohibition.

The commenter has also suggested that we specify which noninvasive testing is exempt from the prohibition on referrals. As mentioned in the response to the previous comment, we believe that the most appropriate way for a physician or clinical laboratory to determine if Medicare considers a diagnostic test to be a clinical laboratory test subject to the requirements of section 1877, is to find out if the test is subject to categorization under CLIA. The Medicare carriers are available to provide this information to individuals and physicians if it is not clear to a physician, other supplier, or provider of services and if they do not have available the latest compiled list of clinical laboratory test systems, assays, and examinations categorized by complexity and published by the CDC. If a test does not appear on a compiled list, a physician or laboratory should contact the CDC at the address we mentioned in the last response in order to be certain, since the lists are not yet complete.

2. Compensation Arrangement

Under the proposed rule (§ 411.351), a compensation arrangement would be any arrangement that involves any remuneration between a physician or a member of his or her immediate family

and an entity. The definition of compensation arrangement was amended by OBRA '93 to exclude certain types of remuneration (identified in section I.D.1.c. of this preamble).

Comment: One commenter indicated that the final regulations need to give a specific definition for the phrase "compensation arrangement," not simply repeat the words that the Congress has provided.

Response: The commenter did not explain why the proposed definition was perceived as insufficient. The words of the definition are specific, and we do not believe they are susceptible to misinterpretation. The definition is broad, because it covers any remuneration between a physician (or an immediate family member) and an entity, and it may be this aspect of the definition that concerned the commenter. We believe, however, that it was the intent of the Congress to include all arrangements (direct and indirect) between physicians and laboratories involving any remuneration. We believe that the statutory definition accomplishes this purpose. In the OBRA '93 amendments, the Congress retained the broad definition of "remuneration" in section 1877(h)(1)(B), but did specifically except from the term "compensation arrangement" a very limited list of arrangements involving the kinds of remuneration listed in section 1877(h)(1)(C). These changes are reflected in this final regulation.

Comment: One commenter indicated that laboratories often must enter into arrangements with physicians, who are not employed by the laboratory, for necessary services. The commenter believed that as long as certain safeguards, comparable to those applicable to arrangements between physicians and hospitals, are met, these arrangements should not be considered compensation arrangements that would prohibit the physicians from making referrals. Examples of such arrangements are (1) an arrangement to review abnormal test results when further medical consultation is required, and (2) a contract with a physician to provide various consultation services, such as reviewing anatomic pathology specimens, interpreting holter monitors or electrocardiograms, and reviewing Pap tests.

Another commenter indicated that, because of the breadth of the self-referral law, any time a laboratory makes a payment to a physician, a compensation arrangement is created. Thus, for example, if a laboratory maintains a self-insured group medical plan and pays physicians directly for

the medical services provided to its employees, it would, in this commenter's view, have a compensation arrangement with those physicians and should not accept Medicare referrals from them. The commenter suggested that these types of legitimate arrangements should not be considered compensation arrangements as long as safeguards are put into place to ensure nonabuse.

Response: What these commenters are asking for is an exception for an arrangement under which a referring physician furnishes services to a laboratory (or, alternatively, that the term compensation arrangement be defined in a manner so as not to include that arrangement). Section 1877(e)(3), as amended by OBRA '93, provides an exception for a compensation relationship in which a laboratory entity pays a physician for personal services furnished under an arrangement. Such an arrangement does not result in the physician being prohibited from making referrals to that entity if certain specific conditions (detailed in section I.D.6.d. of this preamble) are met.

In addition to the exception in section 1877(e)(3), section 1877(e)(2), as amended by OBRA '93, provides that, if a laboratory makes payments to a physician as the result of a bona fide employment relationship with the physician, that physician's referrals would not be prohibited, providing certain criteria are met.

Comment: One commenter stated that in many situations laboratories are required by State or Federal law to have particular arrangements with physicians. For example, under the new CLIA regulations (42 CFR part 493), laboratories may be required to have physicians in a number of different positions in the laboratory. The commenter believed these types of arrangements should not be considered compensation arrangements that would prohibit referrals by the physicians.

Response: As mentioned in an earlier response, it is our belief that most of these arrangements could qualify for either the exception found in section 1877(e)(2) for bona fide employment relationships or, when the physicians are not employed, section 1877(e)(3) for personal service arrangements.

Accordingly, a compensation arrangement between a laboratory and a referring physician for specific identifiable services that has all of the elements required for the subject exceptions would not cause that physician's referrals to be prohibited.

Comment: One commenter noted that laboratories routinely sell services directly to physicians who then