Section 1877(e)(3)(B)(ii) defines a "physician incentive plan" as any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the entity.

On December 14, 1992, we published, at 57 FR 59024, our proposed rule on physician incentive plans. Because there may be entities that were not affected by the proposed rule at the time it was published but are now affected, we plan to publish the final rule with a 60-day comment period so that these newly-affected entities have an opportunity to comment.

As the result of section 152(c) of SSA '94, until January 1, 1995, the provisions in section 1877(e)(3) do not apply to any arrangements that meet the requirements of subsection (e)(2) or (e)(3) of section 1877 of the Act before they were amended by OBRA '93.

### e. Exception—Remuneration Unrelated to Provision of Clinical Laboratory Services

Before OBRA '93, section 1877(b)(4) provided an exception for financial relationships (ownership/investment interests or compensation arrangements) with a hospital unrelated to the provision of clinical lab services. OBRA '93 omits this exception, but replaces it with section 1877(e)(4), which excepts remuneration provided by a hospital to a physician if it is unrelated to the provision of clinical laboratory services. Section 152(c) of SSA '94 amends section 13562(b)(2)(B) of OBRA '93 to reinstate, until January 1, 1995, section 1877(b)(4) as it appeared before OBRA **'93**.

### f. Exception—Physician Recruitment

OBRA '93 retains, at section 1877(e)(5), the provision previously at section 1877(e)(4). The provision provides that remuneration from a hospital to a physician to induce the physician to relocate to the area serviced by the hospital in order to be a member of the hospital's medical staff does not constitute a compensation arrangement for purposes of the prohibition on referrals if certain conditions (detailed in the March 1992 proposed rule) are met.

# g. Exception—Isolated Transaction

OBRA '93 retains, at section 1877(e)(6), the provision previously at section 1877(e)(5). The provision provides that an isolated financial transaction, such as a one-time sale of property or (as added by OBRA '93) a practice, is not considered to be a compensation arrangement for purposes of the prohibition on referrals if certain conditions (detailed in the March 1992 proposed rule) are met.

### h. Salaried Physicians in a Group Practice

OBRA '93 removed, effective January 1, 1992, the provision previously at section 1877(e)(6). That provision had specified that a compensation arrangement involving payment by a group practice of the salary of a physician member of the group practice did not constitute a compensation arrangement that would trigger the prohibition on referrals.

## *i. Exception—Certain Group Practice Arrangements With a Hospital*

OBRA '93 added a new section 1877(e)(7) that provides, effective January 1, 1992, that an arrangement between a hospital and group under which clinical laboratory services are furnished by the group but are billed by the hospital does not constitute a compensation arrangement for purposes of the prohibition on referrals if the following conditions are met:

• With respect to the services furnished to a hospital inpatient, the arrangement is in accordance with the provision of inpatient hospital services under section 1861(b)(3).

• The arrangement began before December 19, 1989, and has continued in effect without interruption since that date.

• With respect to the clinical laboratory services covered under the arrangement, substantially all of these services furnished to patients of the hospital are furnished by the group under the arrangement.

• The arrangement is set out in a written agreement that specifies the services to be furnished by the parties and the amount of compensation.

• The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

• The compensation is provided under an agreement that would be commercially reasonable even if no referrals were made to the entity.

• The arrangement between the parties meets any other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

# *j. Exception—Payments by a Physician for Items and Services*

OBRA '93 added a new section 1877(e)(8), which provides that the following do not constitute compensation arrangements for purposes of the prohibition on referrals:

• Payments made by a physician to a laboratory in exchange for the provision of clinical laboratory services.

• Payments made by a physician to an entity as compensation for items or services other than clinical laboratory services if the items or services are furnished at fair market value.

### 8. Sections 1877(f) and 1877(g)

SSA '94 amends the provisions of section 1877(f), which concern reporting requirements. This section requires each entity providing covered items or services for which payment may be made under Medicare to provide the Secretary with information concerning the entity's ownership, investment, and (as added by SSA '94) compensation arrangements including (1) the covered items and services furnished by the entity and (2) the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in section 1877(a)(2)(A)) in or a compensation arrangement (as described in section 1877(a)(2)(B) with the entity, or whose immediate relatives have such an ownership or investment interest in or who have such a compensation relationship with the entity. OBRA '93 retained the provisions of section 1877(g), which concern sanctions.

### 9. Other Definitions

OBRA '93 amended section 1877(h)(5) and (6) to remove the definitions for "investor" and "interested investor, disinterested investor," effective January 1, 1992.

### II. Published Federal Register Documents

### A. Provisions of the Proposed Rule— Physician Ownership of, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services

As stated earlier, on March 11, 1992, we published in the **Federal Register** a proposed rule that set forth our proposal for establishing in regulations the provisions of section 1877, as amended by OBRA '90, that relate to physician referrals to clinical laboratories. Section 1877 is very specific. For the most part, we believed the definitions set forth in section 1877(h) were detailed and therefore did not require extensive elaboration in regulations. Accordingly,