A hospital located outside of Puerto Rico if one of two specified conditions is met concerning the nature of the ownership.

6. Exceptions Related to Compensation Arrangements

We proposed to add section 411.359 to specify that, for purposes of the referral prohibition, certain compensation arrangements (as defined in the proposed rule) would not constitute a financial relationship if they involve—

• Rental or lease of office space;

• Certain employment and service arrangements with hospitals;

• Certain arrangements connected with physician recruitment;

• Certain isolated financial transactions;

• Certain service arrangements with entities other than hospitals;

• Salaried physicians in a group practice; and

• Other arrangements with hospitals if the arrangement does not relate to furnishing clinical laboratory services.

B. Provisions of the Interim Final Rule With Comment Period—Reporting Requirements for Financial Relationships Between Physicians and Health Care Entities That Furnish Selected Items and Services

The interim final rule with comment period (published December 3, 1991) listed reporting requirements under the Medicare program for the submission by certain health care entities of information about their financial relationships with physicians. It implemented section 1877(f), which includes the requirement that entities furnishing Medicare covered items or services provide us with information concerning their ownership or investment arrangements. (The rule extended the reporting to include compensation arrangements, not just ownership and investment interests.) The December 1991 interim final rule also provided notice of our decision to waive the requirements of section 1877(f) with respect to certain entities that do not furnish clinical laboratory services.

The information submitted was to include at least the name and unique physician identification number (UPIN) of each physician who had a financial relationship with the entity, the name and UPIN of each physician who had an immediate relative who had a financial relationship with the entity and, with respect to each physician identified, the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement, if we requested it).

Any person who, although required to, failed to submit the required information was subject to a civil money penalty of not more than \$10,000 for each day of the period beginning on the day following the applicable deadline established until the information was submitted.

In addition, the interim final rule discussed our decision to waive the reporting requirements for all entities (other than those providing clinical laboratory services) in States other than the minimum number of 10 specified in the statute. In the 10 States we selected, the reporting requirements were waived for entities other than the 6 types enumerated in the statute and section 411.361(c). The waiver represented a balance between our need to obtain sufficient ownership information for meaningful use in developing a statistical profile required by the Congress in section 6204(f) of OBRA '89, as amended by section 4207(e)(4) of OBRA '90, and in evaluating the need for future legislative, policy, or operational actions, and the need to minimize the administrative time and cost involved in collecting and analyzing the information. We believe that by collecting the information from the enumerated entities in the minimum number of 10 States, we satisfied these congressional and administrative needs.

In determining the States in which a blanket waiver would not be granted, we selected 10 States that represented approximately 42 percent of the physicians who bill the Medicare program for items and services furnished to beneficiaries. Medicare contractors servicing all providers and suppliers in the 10 selected States process approximately 40 percent of all Medicare claims. Services provided by the six types of entities specified in the statute account for a significant proportion of Medicare expenditures and represent a cross-section of Medicare covered services. Therefore, we decided to waive the requirements of section 1877(f) with respect to entities (other than those providing clinical laboratory services) in all States except the following: Arkansas, California, Connecticut, Florida, Michigan, Ohio, Pennsylvania, South Carolina, Texas, and West Virginia. These States were selected because they represent: A mix of rural (West Virginia), urban (Florida), and mixed urban/rural States (Ohio, Texas); a variety of claims/bills volume, from very small (Arkansas) to very large (Pennsylvania); and, a geographic spread from north (Michigan) to south

(South Carolina) as well as both coasts (from California to Connecticut).

Note that while the effect of section 1877(f) of the Act and section 6204(f) of OBRA '89 was to require the Secretary to submit to the Congress a statistical profile within 90 days after each calendar quarter, section 4207(e)(4) of OBRA '90 amended OBRA '89 to require only one statistical profile, which was due by June 30, 1992. Clinical laboratory entities reported information about financial relationships with physicians as part of a survey conducted in the fall of 1991, and we used this data in the required statistical profile.

Section 1877(f) authorizes the Secretary to gather information from any entity providing covered items or services in such form, manner, and at such time as she specifies. Thus, the Secretary can again require entities to report whenever she deems it appropriate for purposes of enforcing the referral prohibition in section 1877. Section 152(a) of SSA '94 amended section 1877(f), altering the rules for future reporting. The provision now requires entities to report not only their ownership arrangements with physicians, but also their investment and compensation arrangements. Section 152(a) also eliminated the Secretary's authority to waive the reporting requirements for certain states or services. The Secretary, however, continues to have the right to determine that an entity is not subject to the reporting requirements because it provides Medicare-covered services very infrequently. In addition, the reporting requirements still do not apply to designated health services furnished outside the United States. The effective date of the amendments to section 1877(f) is the date of enactment of SSA '94, that is, October 31, 1994.

III. Principles for Developing This Final Rule With Comment Period

In this final rule with comment, we are adopting the provisions of our March 1992 proposed rule, changed as appropriate to address the comments on the proposed rule and the new requirements relating to clinical laboratory services contained in OBRA '93, as amended by SSA '94, that have a retroactive effective date of January 1, 1992. OBRA '93 provides several exceptions that were not in previous legislation. In some cases, these new exceptions address suggestions received through public comment on the March 1992 proposed rule. It is our intention that this final rule with comment reflect, to the extent possible, the comments on the proposed rule and the new, but retroactive, requirements of OBRA '93,