the collection of useless information will thwart, rather than support, legitimate monitoring efforts. Examples of information that the commenters believed was unnecessary was identifying *all* physicians in a teaching hospital, considering the size of the facility, the number of salaried staff and faculty, and the time and effort required to collect, organize, check, and report the required data.

Response: The scope of the data collection activity was expansive in order to ensure that the Congress had sufficient information on utilization rates by physician owned and nonowned entities to consider in its legislative activities. While this may have appeared to be more data than could be effectively used, we believed a more narrow data collection effort would have resulted in the Congress having insufficient facts when considering legislative alternatives. Surveyed entities were expected to make good faith efforts to complete the surveys accurately, completely, and timely. In addition, we granted extensions to the 60-day response period on a case-by-case basis.

Comment: One commenter opposed the requirement that hospitals report compensation/remuneration arrangements, because the requirement exceeds the scope of section 1877(f) of the Act.

Response: Prior to SSA '94, section 1877(f) did not specifically provide us with the authority to require that hospitals report compensation/ remuneration arrangements. Section 1877(f) required that entities report only the ownership or investment interests of physicians. As we pointed out in the preamble to the interim final rule, however, we believed that other parts of section 1877, the payment provisions of the Medicare statute, and section 6204(f) of OBRA '89, as amended by OBRA '90, implicitly required us to collect this information.

As we pointed out at 56 FR 61376, we need the information on compensation/ remuneration arrangements in order to enforce the general prohibition, in section 1877, against physicians referring to laboratories with which they have a financial relationship, including a relationship based on a compensation arrangement. Without the reporting requirement, we would not have sufficient information to make payment determinations. Also, we would not have had the data we needed to prepare the statistical profile required by section 6204(f) of OBRA '89, as amended by section 4207(e)(4) of OBRA '90. This provision required us to produce a profile that covered all of a physician's

direct or indirect financial interests. As we explained earlier, beginning October 31, 1994, § 152(a) of SSA '94 amended § 1877(f) to explicitly require that a reporting entity provide information concerning the entity's ownership, investment, and compensation arrangements.

Comment: One commenter suggested that the imposition of civil monetary penalties on reporting entities that fail to report compensation/remuneration arrangements in a timely manner exceeds our statutory authority.

Response: Section 1877(g)(5) provides a civil money penalty when a person fails to meet the reporting requirements of section 1877(f). Section 1877(f), prior to OBRA '93, concerned information related to ownership interests only. However, as the result of the changes made in § 1877(f) by § 152(a) of SSA '94, entities are now required to provide information about ownership, investment, and compensation arrangements. As a result, we now have the authority to impose a civil money penalty when an entity fails to provide any of these kinds of information.

Comment: One commenter from California suggested that reporting employee information would place a hospital in jeopardy of violating certain State laws and State regulations.

Response: As we stated in an earlier comment, we have interpreted section 1877, the payment provisions of the Medicare statute, and section 6204(f) of OBRA '89 as requiring that reporting entities provide us with information about all of their financial relationships with a physician or a physician's family member. The statute at § 1877(f) now requires this information for all ownership, investment, and compensation arrangements. If this explicit Federal requirement conflicts with State law or State regulations, the Federal law and Federal regulations prevail.

VI. Provisions of This Final Rule

We have extensively rearranged the regulations from what we proposed and have added numerous OBRA '93 provisions as amended by SSA '94. Because of these many changes, we are including, in section VI.C., a list identifying whether the requirements in this final rule derive from OBRA '93, SSA '94, the proposed rule, or comments on the proposed rule. In addition, we identify below the changes from the December 1991 interim final rule and the March 1992 proposed rule.

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

Based on our analysis of the comments, we are adopting the provisions as set forth in the March 1992 proposed rule, with the following changes. The reason for a change either has been discussed in section IV of this preamble, the change is a result of the provisions of OBRA '93 or SSA '94, or the change merely conforms the regulations to the statute.

• In § 411.1 ("Basis and scope"), we added that section 1877 of the Act sets forth limitations on referrals and payment for clinical laboratory services furnished by entities with which an immediate family member of the referring physician has a financial relationship. This change was made to conform the regulation to the statute.

• As a result of the comments we received, we revised the definition of "compensation arrangement" at § 411.351 ("Definitions") to clarify that it applies to direct and indirect arrangements.

• We revised the definition of "group practice" at § 411.351 as follows:

+ Revised the "substantially all" threshold to 75 percent of the total patient care services of group practice members, measured as "patient care time."

+ Expanded and moved, to a new § 411.360, the requirements related to the group practice attestation statement.

+ Provided an exception to the "substantially all" requirement for those services furnished through a group practice located solely in certain areas designated as HPSAs under § 411.351. Also specified in this section that when members of a group practice that is located outside an HPSA spend time providing services in certain HPSAs, that time is not used to calculate the outside group's "substantially all" standard.

• We removed the definitions of "interested investor" and "investor" from § 411.351.

• We revised the definition of "remuneration" at § 411.351 to provide that forgiveness of debts, certain payments, and the furnishing of certain items, devices, and supplies are not considered remuneration if they meet specified conditions.

• We added a definition of "clinical laboratory services," "direct supervision," "hospital," "HPSA," "laboratory," "members of the group," "patient care services," "physician incentive plan," "plan of care," and "transaction" to § 411.351.