as amended by SSA '94. This final rule with comment also revises the provisions of the December 1991 interim final rule to incorporate the amendments to section 1877(f) made by SSA '94, to apply to any future reporting that we require.

To address the provisions of section 1877 that are effective on January 1, 1995, as provided by OBRA '93, we plan to publish regulations in addition to this one. We will publish a proposed rule to interpret any retroactive provisions contained in OBRA '93 that we believe allow us to exercise discretion in their implementation. In this final rule, we have, in general, only reiterated the new, but retroactive, statutory provisions, incorporating them into our proposals. We have interpreted the new provisions only in the few instances in which it was necessary to do so in order to allow the statute to be implemented at all.

The proposed rule will also cover those provisions of section 1877 concerning physician referrals for clinical laboratory services that became effective on January 1, 1995, as well as those covering the other designated health services (all of which are effective for referrals made on or after January 1, 1995). Finally, we plan to publish a final rule that will address any comments received on this final rule with comment and the new proposed rule.

We are including in this final rule the OBRA '93 provisions related to the following:

• The in-office ancillary services exception.

- The rental of equipment exception.
- The rental of office space exception.

• The bona fide employment relationships exception.

• The personal services and physician incentive plan exception.

• The exception concerning remuneration unrelated to the provision of clinical laboratory services.

• The change in the isolated transactions exception.

 The exception concerning certain group practice arrangements with a hospital.

• The exception for payments by a physician for items and services.

• All changes in definitions in 1877(h) that have a retroactive effective date (compensation arrangement, remuneration, group practice).

# IV. Analysis of and Responses to Public Comments on the Proposed Rule— Physician Ownership of, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services

In response to the publication in the Federal Register of the proposed rule on March 11, 1992, we received 299 timely public comments. The comments came from a wide variety of correspondents including professional associations and societies. health care workers. law firms. third party health insurers, hospitals, and private individuals. We screened each commenter's letter and grouped like or related comments. Some comments were identical, indicating that the commenters had submitted form letters. After associating like comments, we placed them in categories based on subject matter or based on the portion of the regulations affected and then reviewed the comments. All comments relating to general subjects, such as the format of the regulations, were similarly reviewed.

This process identified areas of the proposed regulation that we needed to review in terms of their effect on policy, consistency, or clarity of the rules.

We have presented all comments and responses in, for the most part, the order in which the issues appeared in the March 1992 proposed rule.

Note: We have found it necessary to change the designation of some sections from what was proposed. We have prepared a table, which appears at the end of this preamble, that relates the requirements in this final rule to the correlative proposed sections from which they evolved. If OBRA '93 provisions resulted in significant change, we so identify OBRA '93 as the source. This table is intended merely to assist parties who may be interested in comparing specific provisions as proposed or as contained in OBRA '93 to those of the final rule with comment. It does not supplant the more detailed discussion in this preamble. Unless otherwise indicated, citations in the responses that follow are to the sections as they are designated by this final rule with comment.

## A. General

# 1. Purpose of Final Rule

*Comment:* One commenter requested that the Secretary ensure that the final rule is cast so that its purpose is clear; that is, the rule should be presented so as to support the idea that the ethical delivery of quality, medically necessary care is fundamental to preserving the integrity of medical practice in general as well as the Medicare program in particular.

*Response:* We share the commenter's view. We believe that section 1877 was enacted out of concern over the findings of various studies that physicians who

have a financial relationship with a laboratory entity order more clinical laboratory tests for their Medicare patients than physicians who do not have a financial relationship. There have been at least 10 studies conducted over the past few years that concluded that patients of physicians who have financial relationships with health care suppliers receive a greater number of health care services from those suppliers than do patients generally.

To the extent that section 1877 and this final rule protect against this practice, the Medicare program and its beneficiaries are well served. Therefore, to the extent that physicians and providers of clinical laboratory services change their financial relationships and behavior to comply with provisions of section 1877 and, in turn, reduce overutilization of laboratory services, we believe that this change will have a positive effect on other health insurance programs. One of our prime goals is to ensure that our rules carry out the Congress' mandate in a manner that is in the best interest of all individuals who may be affected by the rules.

#### 2. Delay of Effective Date

*Comment:* Several commenters requested that we delay the effective date of the final rule. One commenter recommended a 60-day delay, another recommended not less than 90 days, and yet another commenter requested not less than 120 days from the date of publication in the **Federal Register** and that application of the regulation should be prospective only.

*Response:* We usually provide for a 30-day delay in the effective date of a final rule. This delay is offered so that affected parties have the opportunity to change their practices, if necessary, to comply with the requirements of the final rule. While we understand that the goal behind the commenters' suggestions is to provide sufficient time for parties affected by this final rule to make arrangements to comply with its requirements, we do not believe that an additional delay in the effective date would be beneficial. This is so primarily because, in this rule, we are establishing additional exceptions from the prohibition on referrals based upon public comments. In addition, we plan to publish a subsequent final regulation that will address any comments received on this regulation.

#### 3. Delay of Enforcement Provisions

*Comment:* One commenter requested that the Secretary indicate that the enforcement of the prohibition on referrals begin no earlier than the effective date of this rule. As a result of