retroactive effective date of January 1, 1992. This final rule with comment, by prohibiting physician referrals for clinical laboratory services by physicians who have certain ownership, investment, or compensation arrangements with the entity furnishing the service, is meant to eliminate the ordering of unnecessary laboratory tests.

According to the OIG report cited in the March 1992 proposed rule (57 FR 8589), at least 25 percent of the nearly 4500 independent clinical laboratories, at the time of the report, were owned in whole or in part by referring physicians. The same OIG report revealed that Medicare patients of referring physicians who own or invest in these laboratories received 45 percent more clinical laboratory services than all Medicare patients. The OIG estimated in its report that the "increased utilization of clinical laboratory services by patients of physician-owners cost the Medicare program \$28 million nationally in 1987." (Financial Arrangements Between Physicians and Health Care Businesses, (May 1989))

We believe the majority of physicians and clinical laboratories do not currently make referrals that are prohibited by this rule. In addition, we believe that, in response to the statutory provisions, many physicians and laboratories took necessary steps, before January 1, 1992, to ensure that their investment and employment activities did not restrict their ability to make referrals. Therefore, any estimate of the aggregate economic impact of this rule will be purely speculative. We believe the statute itself will have a continuing deterrent effect on physicians' aberrant referral patterns and investment interests.

B. Regulatory Flexibility Act

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all hospitals, physicians, and clinical laboratories to be small entities.

In addition, section 1102(b) requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b), we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. We expect that a few entities may be affected to varying degrees by this final rule. Relative to the potential impact on these entities, the following discussion is provided.

1. Impact on Physicians and Physician Groups

Physicians reportedly find it inefficient and inconvenient to split their laboratory referral business among multiple laboratories; the physician who uses one laboratory for private-pay patients is likely to use that same laboratory for all of his or her patients. Therefore, it is conceivable that, absent this rule, a physician could seek an ownership or investment interest in a laboratory, or a compensation arrangement with a laboratory, in order for the physician to share in the profits of the laboratory to which he or she makes referrals. In these cases, the prohibition on referrals might apply, which will require the physician to either dispose of his or her interest in the laboratory or stop referring Medicare patients to that laboratory.

As discussed at length earlier in this preamble, some physicians who have independent practices maintain a physician office laboratory with other physicians in shared premises, with shared equipment, shared employees, a shared administrator who has the power to hire and terminate employees on behalf of the physicians, and shared overhead costs. For the most part, these shared office space arrangements are not eligible for the in-office ancillary exception found in section 1877(b)(2)and, therefore, the prohibition on referrals does apply. Thus, the physicians must each separately meet the in-office ancillary services requirements, form a group practice meeting the definition of section 1877(h)(4) of the Act, dispose of their interest in the shared laboratory facility, or stop referring Medicare patients to that laboratory facility.

Also as discussed earlier, in response to OBRA '93 changes, we have added exceptions to the prohibition on referrals that we believe recognize existing medical practice, are reasonable, and will not result in program abuse.

As a result of public comments we received in response to the proposed rule, we are revising the definition of "group practice" (§ 411.351) by lowering the "substantially all" threshold from 85 percent to 75 percent of the total patient care services of group practice members. This change will allow groups of physicians additional flexibility in hiring part-time and temporary physicians, without the group jeopardizing its standing as a group practice.

2. Impact on Laboratories

As mentioned earlier in this impact statement, the report from the OIG to the Congress indicated that at least 25 percent of the nearly 4500 independent clinical laboratories were owned in whole or in part by referring physicians. The same report found that Medicare "patients of referring physicians who own or invest in these laboratories received 45 percent more clinical laboratory services than all Medicare patients * * *." Other studies found equivalent correlations involving physician self-referrals. However, we are unable to estimate with any degree of accuracy how existing physician laboratory owners will react to the provisions of the law and this rule or how the utilization of laboratory services will change. Nevertheless, given the extensive reach of section 1877 of the Act and these final regulations and the substantial penalties that are provided for violations of the prohibition on referrals, we believe that laboratories and physicians have been restructuring their relationships to ensure compliance with the statute and will continue to do so.

3. Impact on Hospitals

Sections 411.356 (b)(2) and (b)(3) include exceptions related to the prohibition on referrals for ownership or investment interests in certain hospitals. Sections 411.357 (c), (d), (e), (g), and (h) include exceptions related to the prohibition on referrals for compensation for services performed or supervised by physicians. Because we believe that a large number of the financial relationships between physicians and hospitals are covered by these exceptions, we do not believe hospitals will be significantly affected by this rule. In addition, hospitals in Puerto Rico and many hospitals in rural areas are excluded from this rule under §411.356(c).

For the reasons stated above, we have determined, and the Secretary certifies, that this final rule with comment will not result in a significant economic impact on a substantial number of small entities or on the operations of a substantial number of small rural hospitals. We are, therefore, not preparing analyses for either the RFA or section 1102(b) of the Act.

In accordance with the provisions of E.O. 12866, this regulation was reviewed by the Office of Management and Budget.