- We revised § 411.355 ("General exceptions to referral prohibitions related to both ownership/investment and compensation") to do the following:
- + For purposes of the in-office ancillary services exception in § 411.355(b), require that individuals furnishing services be "directly" supervised by the referring physician or by another physician in the same group practice. (The proposed rule had required that services be provided by an employee who was "personally" supervised by these physicians.)
- + Include among the locations where the service may be furnished a building that is used by the group practice for the provision of some or all of the group's clinical laboratory services. (The proposed rule had required that the building be used by the group practice for centrally furnishing the group's clinical laboratory services.)
- We added the following services to the general exceptions listed under § 411.355 ("General exceptions to referral prohibitions related to both ownership/investment and compensation"):
- + Services furnished by a qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act) to individuals enrolled in the organization (new § 411.355(c)(4)).
- + Services furnished in an ASC or ESRD facility or by a hospice and included in the ASC rate, ESRD composite rate, or per diem hospice charge, respectively (new § 411.355(d)).
- We revised proposed § 411.357, now designated as § 411.356, ("Exceptions to referral prohibitions related to ownership or investment interests") to—
- + Revise the requirements relating to publicly-traded securities, as specified in section 1877(c) of the Act (as amended by OBRA '93 and SSA '94), to include securities which "may be purchased" on terms generally available to the public, which can be those traded on additional stock markets, and which can be in corporations that had the following:
- Until January 1, 1995, total assets at the end of the corporation's most recent fiscal year exceeding \$100 million, or
- —Stockholder equity exceeding \$75 million at the end of the corporation's

- most recent fiscal year, or on average during the previous 3 fiscal years
- + No longer specify, with regard to the corporation's assets, that these assets must have been obtained in the normal course of business and not for the primary purpose of qualifying for the exception;
- + Expand the exception to include mutual funds that constitute ownership in shares in certain regulated investment companies, if the companies had, at the end of their most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75 million.
- + Until January 1, 1995, retained the exception for a hospital located outside of Puerto Rico based on the condition that the referring physician's ownership or investment interest does not relate to the furnishing of clinical laboratory services.
- + Revise the requirements relating to rural providers, as specified in the proposed rule, to delete paragraph (ii), which added the requirement that the majority of tests referred to the rural laboratory are referred by physicians who have office practices located in a rural area.
- + Revise the requirements relating to rural providers, as specified in the proposed rule, to include the requirement that substantially all of the tests furnished by the entity are furnished to individuals residing in a rural area.
- We revised proposed § 411.359, now designated as § 411.357, ("Exceptions to referral prohibitions related to compensation arrangements") to do the following:.
- + Revise (a)(1) to reflect new requirements specified by OBRA '93 for the rental of space.
- + Remove proposed paragraph (a)(2), which contained requirements related to a physician who has an ownership or investment interest in a laboratory and who also rents or leases space to the laboratory.
- + Add an exception for rental of equipment under certain conditions (new § 411.357(b)).
- + Add an exception for certain group practice arrangements with a hospital (new § 411.357(h).
- + Add an exception for payments by a physician to a laboratory or other

- entity in exchange for certain items and services (new § 411.357(i)).
- + Replace proposed § 411.359(b) ("Employment and service arrangements with hospitals") and proposed § 411.359(f) ("Salaried physicians in a group practice") with a new § 411.357(c) ("Bona fide employment relationships"). New § 411.357(c) is based on the exception at section 1877(e)(2) of the Act.
- + Replace proposed § 411.359(e) ("Service arrangements with non-hospital entities") with a new § 411.357(d) ("Personal service arrangements"). New § 411.357(d) is based on the exception at section 1877(e)(3) of the Act.
- We added a new § 411.360 that requires that a group practice submit annually a statement attesting that it met the "substantially all" test set forth, under the definition of "group practice," in § 411.351 of this rule. This section also specifies how a newlyformed group practice meets the "substantially all" criterion.

In addition to the above changes, we have made technical changes. For example, in proposed § 411.355(c)(1), we cross-referenced part 417, subpart C. Subpart C has been redesignated by a new rule. The applicable provisions being cross-referenced are now under subparts J through M. We have also made editorial changes that do not affect the substance of the provisions.

B. 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 published on December 3, 1991, is revised to incorporate the amendments to section 1877(f) made by SSA '94, to apply to any future reporting that we require. However, providers will not be held to the reporting requirements under section 1877(f) until we develop and issue the proper form and accompanying instructions booklet. Until that time, we will use audits and investigations as the primary tools to evaluate compliance with these provisions.

C. Source of Final Regulations.

Final regulations	Source
	Proposed § 411.1.
§ 411.350 Scope of subpart	Proposed § 411.350, SSA '94.
§ 411.351 Definitions	§ 411.351.
Clinical laboratory services	Comments.
Compensation arrangement	Proposed § 411.352 and comments.
Direct supervision	Comments and OBRA '93.