- 4. Technical Change
- 5. Refunds
- E. General Exceptions to Referral Prohibitions Related to Ownership and Compensation
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- 2. In-office Ancillary Services
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- F. Exceptions to Referral Prohibitions Related to Ownership or Investment Interest
- 1. Publicly-traded Securities
- 2. Rural Laboratories
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- G. Exceptions to Referral Prohibitions Related to Compensation Arrangements
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- VI. Provisions of this Final Rule
 - A. Proposed Rule—Physician Ownership of, and Referrals to, Health Care Entities that Furnish Clinical Laboratory Services
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 Financial Relationships between
 Physicians and Health Care Entities that
 Furnish Selected Items and Services
 - C. Source of final regulations
- VII. Collection of Information Requirements VIII. Regulatory Impact Statement

I. Legislation and Regulations— Chronological Background

In section 6204 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Public Law 101–239, enacted on December 19, 1989), the Congress added a provision to the Social Security Act (the Act) that governs whether physicians who have financial relationships (or who have immediate family members with financial relationships) with a health care entity can refer Medicare patients to that entity for clinical laboratory services. This provision was amended by section 4207(e) of the Omnibus Budget

Reconciliation Act of 1990 (OBRA '90) (Public Law 101-508, enacted on November 5, 1990); section 13562 of the Omnibus Budget Reconciliation Act of 1993 (OBRA '93) (Public Law 103-66, enacted on August 10, 1993); and section 152 of the Social Security Act Amendments of 1994 (SSA '94) (Public Law 103-432, enacted on October 31, 1994). As discussed below, we published an interim final rule in 1991 concerning financial relationship reporting requirements, and we published a proposed rule in 1992 concerning physician referrals to clinical laboratories.

A. OBRA '89

Section 6204 of OBRA '89 added section 1877, "Limitation on Certain Physician Referrals," to the Act. (Unless otherwise indicated, all references below to various sections of the law are references to the Act.) In general, section 1877 as added by OBRA '89 prohibits a physician with a financial relationship with an entity that furnishes clinical laboratory services (or a physician with an immediate family member who has such a relationship) from making a referral to that entity for clinical laboratory services for which Medicare would pay. It also prohibits the entity from billing Medicare, an individual, a third-party payor, or other entity for an item or service furnished as a result of a prohibited referral. Additionally, it requires a refund of any amount collected from an individual as the result of a billing for an item or service furnished under a prohibited referral. The statute provides for certain exceptions to the prohibition.

B. OBRA '90

Section 4207(e) of OBRA '90 amended certain provisions of section 1877 to clarify definitions and reporting requirements relating to physician ownership and referral and to provide an additional exception to the prohibition.

C. Federal Register Documents

On December 3, 1991, we published an interim final rule in the **Federal Register**, at 56 FR 61374, that set forth reporting requirements under the Medicare program for health care entities furnishing clinical laboratory services (and certain other services as discussed below) to submit information about their relationships with physicians. On March 11, 1992, we published a proposed rule in the **Federal Register**, at 57 FR 8588, that proposed regulations concerning the provisions of section 1877, as amended by OBRA' 90, concerning physician

referrals to clinical laboratories. Although we summarize the provisions of the interim final rule and proposed rule in section II of this document, readers may want to refer to the interim final rule and proposed rule for additional information on the statutory provisions as amended by OBRA '90 and for the specifics of our proposals.

D. OBRA '93 and SSA '94

Section 13562 of OBRA '93 included extensive revisions to section 1877. Some of the revisions simply elaborate on or amend existing law, while others institute entirely new provisions. With regard to referrals for clinical laboratory services, some of the provisions of OBRA '93 have a prospective effective date of January 1, 1995, while others have a retrospective effective date of January 1, 1992. Most dramatically, section 13562 extends section 1877 to cover 10 additional designated health services, beginning with referrals made after December 31, 1994.

In addition, section 13624 added paragraph (r) to section 1903. This section extends certain provisions of section 1877 to the Medicaid program effective on or after December 31, 1994. That is, this section prohibits Medicaid payments to a State for designated health services furnished on the basis of a referral that would result in the denial of payment under Medicare if Medicare provided for coverage of the service to the same extent and under the same terms and conditions as under the State plan. This section also provides that the reporting requirements under 1877(f) and the civil money penalty provisions for failure to report information under section 1877(g)(5) apply to entities that furnish services covered under the Medicaid program in the same manner as they apply to entities that furnish Medicare covered services.

SSA '94 amended the reporting requirements that entities providing Medicare (and now Medicaid) items and services have to meet for purposes of the referral prohibition, changed some of the designated health services, and altered the effective date provisions in OBRA '93. The changes in the effective date provisions have altered the dates on which some of the provisions relating to referrals for clinical laboratory services go into effect prior to January 1, 1995. These changes have been reflected in this final rule.

A separate notice of proposed rulemaking will be published to address those provisions of OBRA '93 that relate to designated health services (including clinical laboratory services) and that become effective January 1, 1995. In other words, the discussion in this