this suggestion, any physician who is out of compliance with section 1877 before that effective date would be held harmless under the final rule.

Another commenter requested that we postpone the implementation of sanctions, at the very least, until 90 days after the final rule has been issued.

Response: Section 1877(g) of the Act sets forth several enforcement provisions that apply to prohibited referrals for clinical laboratory services and to prohibited claims for payment for these services.

• Section 1877(g)(1) provides for denial of Medicare payment for a clinical laboratory service furnished as the result of a prohibited referral.

• Under section 1877(g)(2), if a person collects any amounts that were billed for services furnished under a prohibited referral, a timely refund of each amount is required.

• Section 1877(g)(3) authorizes the imposition of civil money penalties of not more than \$15,000 for each such service and possible exclusion from the Medicare and other programs for any person that presents, or causes to be presented, a bill or a claim for a clinical laboratory service that the person knows or should know was unlawfully referred or for which a refund has not been made.

 Under section 1877(g)(4), civil money penalties of not more than \$100,000 for each arrangement or scheme and possible exclusion from participation in the Medicare and other programs are authorized in cases in which a physician or an entity enters into a circumvention arrangement or scheme (such as a cross-referral arrangement) that the physician or entity knows or should know has a principal purpose of ensuring referrals by the physician to a particular entity that would be unlawful under section 1877 if made directly. (See the final rule with comment published by the Office of Inspector General on March 31, 1995 (60 FR 16580) for further information. That rule addresses sections 1877(g)(3)and (g)(4).)

The first commenter appears to be suggesting that these statutory enforcement provisions should not be applied until the effective date of this final rule and that a physician who is not in compliance with the provisions of the statute at the time the final rule is published should be held harmless until the effective date of the final rule. The second commenter suggested a 90day delay in application of any sanctions following publication of the final rule.

We disagree with these suggestions. First, many of the provisions of section

1877 of the Act were effective on January 1, 1992, by operation of law. These provisions are, for the most part, self-implementing. This rule incorporates into regulations statutory requirements that are already in effect, clarifying or interpreting certain provisions, and exercising the Secretary's authority to promulgate additional exceptions through regulations. Even though the requirements of this final rule are effective later than the effective date of the statute, we cannot postpone the statutory effective date. Nonetheless, any sanctions that can be applied only as a result of the clarification or interpretation of the statute specified in this rule will, of course, be applied prospectively, beginning with the effective date of this rule.

Section 1877(f) of the Act sets forth certain reporting requirements with which entities were to comply by October 1, 1991. Under this authority, we conducted a survey in the fall of 1991 concerning physician ownership in, and compensation arrangements with, entities furnishing clinical laboratory services. Based on data gathered from that survey, Medicare carriers have already been denying some claims for laboratory services furnished by a laboratory that is independent of a physician's office and that are furnished in violation of the prohibition on referrals. Similarly, the Office of the Inspector General could impose sanctions if, for example, a clinical laboratory has failed to refund an amount that it collected for a service furnished as the result of a referral if the laboratory knew the referral was prohibited.

4. Good Faith Standard

Comment: One commenter suggested that the final rule have either a good faith standard or a provision that the statute will not be violated unless the physician or the laboratory has actual knowledge of a prohibited referral. The commenter requested that the final rule specify the scope of the inquiry required and define the extent of the duty imposed upon laboratories and physicians to determine the relationship of persons that would affect their ability to refer laboratory work or to accept a referral.

Response: It is important to emphasize that the statute and this rule do not prohibit financial relationships that exist or might be established between physicians and entities providing clinical laboratory services. What is prohibited are certain referrals for clinical laboratory testing of Medicare patients. The statute itself, at

section 1877(a)(2), describes "financial relationship" for purposes of determining whether a referral is prohibited. And, as discussed above, section 1877(g) specifies several sanctions that may be applied if a physician or an entity billing for a Medicare covered clinical laboratory service violates the statute's requirements. Thus, unless an exception applies, the statute operates automatically under its own terms to prohibit referrals for Medicare-covered clinical laboratory services to be performed by an entity with which the physician or an immediate family member of the physician has a financial relationship.

We understand that this commenter is advocating adoption of a policy that would hold harmless a physician or laboratory if there is no intention on the part of either to seek an advantage from an ownership interest or compensation arrangement. The commenter is also concerned that a physician or a laboratory may be unintentionally involved in a relationship that would call the physician's referrals into question. Similarly, a laboratory may be unaware that it has a relationship with a referring physician's relatives that would cause the prohibition to apply. However, the statutory prohibition against referrals in such situations applies because of the existence of the financial relationship, not because of the intent of the physician or laboratory or because there is actual knowledge of the relationship. It is the responsibility of physicians and laboratory entities to take whatever steps are necessary to ensure that they do not violate Federal law.

5. Physician Ownership of Health Care Facilities

Comment: One major national medical organization indicated that it believed ownership of health care facilities by referring physicians is an issue that should be addressed, and it supported the proposed rule. It believed there is increased evidence that, when physicians have a financial relationship with an entity, the relationship adversely affects patient care and adds to the cost of health care in the United States. Therefore, the organization believed that physicians should not have a direct or indirect financial interest in diagnostic or therapeutic facilities to which they refer patients, and it indicated support for legislation and regulations that would eliminate this conflict of interest by prohibiting such ownership arrangements in health care.