is silent on when the amendments would apply to a provision that has no nexus with referrals. If section 152 is silent on this issue, we believe that the effective date is the date of enactment of the amendments, which is October 31, 1994. We have incorporated the amendments to section 1877(f) into § 411.361, to apply to any future reporting that we require.

Below we summarize and respond to comments we received in response to the interim final rule with comment period that was published in the **Federal Register** on December 3, 1991 (56 FR 61374). We received timely comments from five organizations.

Near the end of calendar year 1991, we developed a questionnaire titled "Survey of Financial Relationships Between Physicians and Selected Health Care Entities" (form HCFA-95) and forwarded it to selected hospitals, ESRD facilities, suppliers of ambulance services, entities furnishing diagnostic imaging (including magnetic resonance imaging, computerized axial tomography scans, ultrasound, and other diagnostic imaging services), parenteral and enteral suppliers, and entities furnishing physical therapy services. (This survey was also known as the "Ten State Survey.") This process was a collection of information concerning the financial interest arrangements of any entity that furnishes selected items and services for which payment may be made under Medicare. The survey was to be completed by all entities furnishing the above listed covered items and services to Medicare beneficiaries. The scope of the survey was limited to entities in the following 10 States: Connecticut, Pennsylvania, West Virginia, South Carolina, Florida, Michigan, Ohio, Texas, Arkansas, and California.

Surveys were sent to those entities that submitted claims to the Medicare intermediary or carrier for more than 20 items or services in any of the selected categories during calendar year 1990. Originally, an entity was required to return the survey not more than 30 days after the entity received it. Shortly after December 3, 1991, the date contractors were instructed to send the surveys via overnight, certified mail, the response time was extended from 30 days from the date of receipt to 60 days from the date of receipt.

Two commenters applauded our citing the need for the survey because of the potential for abusive behavior in situations where the referring physician has an ownership interest in the facility to which he or she refers patients. A discussion of other comments and our responses to them follow.

Comment: One commenter suggested that requiring the completed survey to be submitted before or at the same time that the comments on the interim final rule were due made the opportunity to comment meaningless.

Response: We agree that the timing of the deadlines for the completed survey and the comments on the interim final rule could be regarded as having had the effect of reducing a commenter's ability to have an impact on that particular survey. As we pointed out in the preamble to the interim final rule, however, section 4207(k) of OBRA '90 authorized the Secretary to issue interim final regulations for the amendments to the Medicare statute. In the preamble, we explained the pressing need for the interim final rule in order for us to fulfill several legislative requirements within their prescribed deadlines. These included carrying out the survey requirements of section 1877(f), as amended by OBRA '90, obtaining adequate information from health care entities in time to apply the payment provisions in section 1877, as amended by OBRA '90, and preparing the statistical profile required by OBRA '89, as amended by OBRA '90.

The purpose of the interim final rule was primarily to notify the public of the decisions the Secretary had made on the few items of discretion left to the Secretary under OBRA '90, such as the selection of the States in which the survey would be administered (the legislation prescribed a minimum of 10 States). In addition, we do not regard the opportunity that was provided to comment on the interim final rule as meaningless. Section 1877 allows the Secretary to collect the survey information in such form, manner, and at such times as she specifies, as long as it is first collected no later than October 1, 1991. The Secretary will take the comments into account if she decides to survey the entities again.

Comment: One commenter suggested that we extend the time for responding to the survey by 60 days and announce the extension publicly.

Response: As noted, we did provide for an automatic extension of 30 days, allowing a total of 60 days for response. We provided 19 representative specialty societies, for example, the American Medical Association, the American Hospital Association, and the American College of Radiology, with this information to alert their members. In addition, we alerted Medicare contractors who, in turn, alerted providers via updates in their routinely distributed bulletins and newsletters.

Comment: One medical specialty association had received several

complaints from its members concerning the question of who must report the ownership interest and what information must be reported. The association stated that the definition of "entity" (physicians, suppliers, or providers) in the instructions was too broad.

Response: The statute at section 1877(f) required, prior to SSA '94, that "[e]ach entity providing covered items or services for which payment may be made under [Medicare] shall provide the Secretary with the information concerning the entity's ownership arrangements, * * *." (Emphasis added.) The statute does not define an "entity." Thus, we could include within this concept any individuals or groups that provided Medicare covered items or services. We surveyed every entity, regardless of type, that provided more than 20 services in 1990 from the minimum set of services (hospital services, ambulance services, etc.) covered by the statutory requirement for this study. The use of the terms "physicians, suppliers, or providers" in our survey instructions was meant to cover all types of entities that had provided more than 20 services during 1990 of the types listed in the legislation.

Comment: One commenter wrote that there was no question on the survey that distinguished between those physicians who have an ownership interest in a facility and those who do not, like hospital-based radiologists. The commenter recommended that information relative to hospital-based practices be extracted and excluded from the study as it could produce a flawed database.

Response: We are not certain of the point this commenter wanted to make. Our survey form clearly distinguished between physicians with an ownership interest in an entity and physicians compensated by an entity, such as hospital-based radiologists. After receiving these survey forms, we matched data from the forms to Medicare claims data to determine referral patterns to entities that had submitted these survey forms. Since we also had information for each entity billing the program relating to whether the patient was referred to the entity by a physician with an ownership interest or by a physician compensated by the entity, the study was able to determine the referral patterns to that entity in a totally objective manner.

Comment: Two commenters wrote that the regulations would result in unreasonably burdensome reporting obligations for certain health care entities. The commenters believed that