incorrect when applied to stock ownership in a corporation that does not itself furnish clinical laboratory services. In the latter case, the assets requirement would apply to the parent corporation (the corporate entity in which the stock is held), not to the subsidiary laboratory corporation.

Therefore, we are clarifying that only the assets of the corporation in which the physician or immediate family member's stock is held may be counted to determine whether the \$100 million asset requirement (or \$75 million in stockholder equity requirement) is met under section 1877(c)(1).

Comment: One commenter indicated that we should permit the grandfathering of financial transactions that were entered into to meet the intent of the legislation with regard to the \$100 million asset test if they were entered into before the effective date of the regulations. The commenter believed that such grandfathering would ease accounting and reporting requirements. Further, the commenter suggested that the final regulations should apply to an organization's fiscal year beginning after the effective date of the rule.

Response: As discussed earlier in this preamble, we are withdrawing our interpretation concerning how a corporation had to have obtained its assets.

In regard to the commenter's suggestion that the final regulations should apply to an organization's fiscal year beginning after the effective date of the rule, we disagree. Section 1877(c)(2), prior to its amendment by OBRA '93, required that a corporation have, at the end of the corporation's most recent fiscal year, total assets exceeding \$100 million. The amended version of this provision requires that a corporation have, at the end of the corporations most recent fiscal year, or on average during the previous 3 fiscal years, stockholder equity exceeding \$75 million. These statutory provisions require an assessment of a corporation's assets or equity based upon a past year or years. These provisions were effective retroactively to January 1, 1992. We do not believe they can be interpreted to require compliance in the fiscal year occurring subsequent to the publication of this final regulation.

2. Rural Laboratories

In proposed section 411.357(b), we stated that an ownership or investment interest in a laboratory that is located in a rural area will not prohibit the physician owners from making referrals if the following criteria are met:

• The laboratory testing that is referred by a physician who has an

- ownership or investment interest in the rural laboratory must either—
- + Be performed on the premises of the rural laboratory; or
- + If not performed on the premises, the laboratory performing the testing must bill the Medicare program directly for the testing.
- The majority of tests referred to the rural laboratory must be referred by physicians who have office practices located in a rural area.

As mentioned in response to a previous comment, we have amended the standards for this exception by eliminating the requirement that a majority of tests referred to the rural laboratory must be referred by physicians who have office practices located in a rural area. Instead, we are adopting the standard required by OBRA '93 that substantially all of the clinical laboratory services furnished by the entity are furnished to individuals residing in such a rural area.

a. General

Comment: One commenter indicated support for our formulation of the exception applicable to laboratories located in a rural area. The commenter was aware of a number of laboratories that were established in rural areas but that serve physician-owners and patients located in large metropolitan areas.

Another commenter stated that this exception protects against abuses by laboratories in rural areas, such as the setting up of a "shell" laboratory with a rural address. This commenter also supported the proposed rule's mandate that at least 51 percent of the tests referred to a rural laboratory be referred by rural doctors. The commenter believed this requirement should help to ensure that the laboratory is in fact serving rural beneficiaries.

On the other hand, a third commenter proposed that the final rule adopt an expanded definition of rural area that would include towns or similar State governmental subdivisions if the population is below 10,000 people and a laboratory located in the area meets the 2 additional requirements set out in the proposed rule. As an additional criterion, the commenter suggested that governmental subdivisions meeting this population standard could be defined as "rural" only if the number of outpatient laboratories in the area was no more than two. The commenter believed that this additional criterion would identify those laboratories that are clearly essential to serving the patient needs of the community.

Response: We agree with the first two commenters and believe that the OBRA

'93 amendment imposing the requirement that "substantially all" of a rural laboratory's services be performed for residents of the rural community indicates that the Congress is aware of and is concerned about the potential for abuse in this area.

What the third commenter urges is recognition of a laboratory entity as a rural provider, despite the fact that the entity is located within a metropolitan statistical area (MSA), if the suggested conditions are met. While we recognize that there may be some laboratory entities located in MSAs that, by virtue of being located in small towns within an MSA, have experiences similar to laboratories located in rural areas, we believe that it would be difficult in any given case to prove that the laboratory's situation actually parallels the situation in a rural area. In addition, it would be difficult and burdensome to make these determinations on a case-by-case basis. Further, at this time, we have no evidence that opening this exception to "nonrural" laboratories would be free of any risk of program or patient abuse, the standard that must be met under section 1877(b)(4).

b. Percentage of Tests and Direct Billing

Comment: One commenter argued that the exception for clinical laboratories in rural areas is too stringent. The commenter was concerned that the proposed requirement that more than 50 percent of the tests performed be referred by physicians whose practices are located in rural areas may present an undue burden on already existing rural laboratories. Those rural laboratories may be forced to close because their viability comes from nonrural business. Thus, the commenter recommended grandfathering existing rural laboratory practices.

Response: Although we have changed the proposed rule, the rule still requires that "substantially all" of a laboratory's services be furnished as rural business. As we explained previously, we believe to meet this standard that at least 75 percent of the clinical laboratory services must be furnished to individuals who reside in a rural area. Section 1877 does not contain an overall "grandfather" clause which would allow laboratory facilities that existed prior to its effective date to continue to accept prohibited referrals just because the laboratories predate the statutory provision. In addition, the statute does not routinely excuse certain referrals because it would be a burden for a facility to alter its business practices in order to fit within an exception. We believe that, instead, the specific