purpose of the statute is to require laboratory facilities to alter their practices in order to avoid abusive or potentially abusive financial relationships. Our approach in the proposed and final regulation for this provision reflects that purpose.

Furthermore, we do not believe that we can specifically except from the prohibition rural laboratories whose viability depends on non-rural business. We do not know at this time how many rural laboratories would have extreme difficulty meeting the requirements in the proposed regulation. Also, as described in previous comments, the situation described by the commenter can result in "shell" laboratory arrangements or otherwise be subject to patient and program abuse.

Comment: One commenter recognized the need to prohibit circumvention schemes by urban laboratories through the rural exemption, but thought that the proposed criteria may have a negative impact on a legitimate rural laboratory as follows: The criteria require laboratory testing referred by an investor physician to be performed on the premises or, if referred to another laboratory, that the testing be billed to Medicare directly by the laboratory performing the tests. This provision would prohibit rural laboratories from referring a limited number of tests to other laboratories and billing for the tests, in accordance with present statutory and regulatory requirements concerning shell laboratories.

One commenter indicated that, if a rural laboratory is not able to bill for reference work, it will be forced to collect patient information and forward it to the reference laboratory. This is necessary to enable the reference laboratory to bill Medicare. The rural laboratory will still be collecting the specimens for forwarding to the reference laboratory, but without compensation. The commenter also maintained that the rule will threaten the ability of small rural laboratories to maintain investment and employment while, on the other hand, the rule rewards large laboratories that already have the advantage of lobbying strength that can affect legislation. Also, the rule will not save the taxpayer any money, as good diagnostics for both treatment and preventive medicine are not a function of who bills Medicare for the tests.

This commenter suggested the following alternatives:

• Eliminate the condition that rural laboratories must perform in-house laboratory testing in order to bill Medicare directly.

• Revise the conditions to read: "if all tests are not performed on the premises, 80 percent of referrals must be made by physicians who have office practices in rural areas and 67 percent of all tests must be performed on the premises, otherwise the laboratory performing the testing must bill the Medicare program directly."

*Response:* We agree that the requirements we proposed for ownership in a rural laboratory are different from those found in the so called "shell laboratory" provision (section 1833(h)(5)(A)). Under the shell laboratory provision, payment may be made to a referring laboratory for the services of a reference laboratory in any of the following circumstances: the referring laboratory is located in, or is part of, a rural hospital; the referring laboratory is wholly owned by the reference laboratory; the referring laboratory wholly owns the reference laboratory; both the referring laboratory and the reference laboratory are wholly owned by the same entity; or not more than 30 percent of the clinical diagnostic laboratory tests for which the referring laboratory (other than a laboratory described in the "wholly owned" provision) receives requests for testing during the year in which the test is performed are performed by another laboratory. These provisions apply to the payment of Medicare-covered clinical diagnostic laboratory services generally. Section 1877 and these regulations contain additional specific requirements that apply to referrals for clinical laboratory services by physicians who have a financial relationship with the laboratory.

In the proposed rule, we stated that 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. Section 1877(d)(2)specifically provides the exception for referrals for clinical laboratory services if the laboratory furnishing the service is in a rural area. We do not believe the exception is satisfied if the rural laboratory in turn refers the work to a laboratory in a nonrural area.

In addition, we do not see this requirement as conflicting with the more general shell laboratory provision, because our requirement applies specifically to the testing ordered by a physician who has a financial relationship with the laboratory. Thus, all other testing referred to the rural laboratory would be subject to the more lenient provisions of section 1833(h)(5)(A) mentioned above. We continue to support this position. It is our firm belief that the Congress provided the rural provider exception in order that beneficiaries living in rural areas would have access to clinical laboratory services that might not be available without the financial investments of local physicians. Without the safeguards included in this regulation, we believe it would be possible to defeat the purpose of the exception.

## c. Future Reclassification of Rural Areas

*Comment:* One commenter indicated that the final rule should provide that laboratories that currently qualify under the rural exception will not be disqualified in the future based on metropolitan statistical area (MSA) reclassification. This clarification will provide stability to legitimate rural laboratories and avoid future uncertainty and future "fireside" sales.

*Response:* We do not believe the language in section 1877(d)(2) is susceptible to the suggested "clarification." The statute specifically requires that a rural provider be located in a rural area as defined in section 1886(d)(2)(D).

Thus, a provider must be located in such an area, even if the MSAs are at some point reclassified for prospective payment purposes. In addition, we do not believe we should provide an additional exception for a rural provider whose area has ceased to be rural, since we have no evidence that the exception would be free from all risk of program or patient abuse.

## 3. Hospitals Outside of Puerto Rico

The OBRA '93 amendments to section 1877 substantially changed the provisions that directly concern physician/hospital relationships. Listed below is a table explaining the provisions prior to OBRA '93 and after OBRA '93, as they are in effect until January 1995; the table also reflects amendments made by SSA '94.