value, without triggering the prohibition. These exceptions apply to relationships with all laboratory entities, including those located in rural areas, provided the conditions set forth in the statute and this final regulation are met.

11. Case-by-Case Exemptions

Comment: One commenter indicated that we should institute a process by which a laboratory may request an exemption from the law on an individual basis, based upon a determination by the Secretary that enforcement of the prohibition against the laboratory would not be in the public interest. The commenter suggested that narrow guidelines should be established for the types of laboratories that would be eligible to apply for this exemption. Thus, in the commenter's view, the administrative burden would not be prohibitive. The commenter proposed that, in order to be eligible for review, that any one of the following criteria be met:

• The laboratory is wholly owned by one referring physician or one group practice. This requirement would exclude the physician joint venture type laboratories, which this commenter believed are the entities intended to be regulated by the law.

• Referrals to a laboratory by physicians who have financial relationships with the laboratory do not exceed a specified percentage of the total laboratory volume. The commenter suggested that the referrals be limited to 40 percent of the laboratory's total volume, consistent with the Medicare anti-kickback investment safe harbor volume criterion. (See 42 CFR part 1001.)

• A laboratory located in a town or similar-type population center with a population of 10,000 or under should be eligible for exemption review if it is the sole outpatient provider of certain laboratory services within that locality. This would recognize that localities that are within an MSA may, in fact, be small towns lacking adequate outpatient laboratory services.

Response: We do not agree that we should implement such a process. Section 1877(b)(4) specifies that, in addition to the exceptions described in the statute, the section 1877(a)(1) prohibition will not apply with respect to any other financial relationship which the Secretary determines, *and specifies* in *regulations*, does not pose a risk of program or patient abuse (emphasis added). The statute speaks in terms of excepting particular financial relationships according to rules that would apply to any person or entity that has such a relationship. It does not authorize "case by case" exceptions.

In addition, we do not believe that the guidelines suggested by the commenter to single out those who are eligible for case-by-case review would provide a guarantee against patient or program abuse. It is not clear to us why the review should only be available when a laboratory is wholly owned by one referring physician or one group practice. The commenter's second guideline would allow a laboratory entity to derive 40 percent of its business from referrals by physicians with whom the entity has a financial relationship. We do not believe that this standard would, in any way, satisfy the requirement under section 1877(b)(4)that exceptions beyond those specified in the law pose no risk of program or patient abuse. We simply do not see how a standard excusing any percentage of referrals would guarantee no risk of abuse.

Finally, we understand that it might be possible that a laboratory located within an MSA could have its existence threatened if it cannot accept referrals from physicians with whom it has financial relationships. The commenter did not, however, identify any specific localities, so we cannot tell how likely it is for this to occur. In any case, any such exception must be shown to comply with the "no abuse" criterion, and the commenter has provided us with no evidence that such an exception would be free of abuse. For these reasons, we are not adopting this suggestion.

12. Physician Ownership of Public Companies

Section 411.357(a)(2) of the proposed regulation provided an exception for a physician's or family member's ownership in a publicly owned corporation, provided that the ownership interest met certain requirements. Among these were the requirement that the corporation have, at the end of its most recent fiscal year, total assets exceeding \$100 million. This requirement reflected section 1877(c)(2) of the statute. OBRA '93 amended the statute to require, instead, stockholder equity exceeding \$75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. SSA '94 made this amendment effective retroactive to January 1, 1992. However, it also provided that, until January 1, 1995, a corporation could still meet the requirement in the exception if it qualified under the pre-OBRA '93 standard.

Comment: One commenter suggested that we create an exception allowing physicians to own shares in clinical laboratories that satisfy the first test of the statutory public-company exception (having publicly-traded securities on the specified national securities exchanges) whether or not the company has \$100 million in assets (as required in proposed § 411.357(a)(2)), under certain conditions.

The conditions suggested were that: (1) The total physician ownership of each class of securities of the entity is less than 20 percent, and (2) no one physician's ownership of any class of securities of the entity represents more than 5 percent of the class. The commenter believed that such ownership would not pose a risk of abuse under Medicare. For example, the stock of Laboratory Corporation A, which has assets of \$50 million, is owned by the following individuals. Laboratory Corporation A has only one class of stock.

Individual	Per- cent- age
Dr. Abe Mr. Brown Dr. Car Mr. Dorr Dr. Else Mr. Frank Mr. Green Mr. Hann	5 17 5 17 5 17 12 12
	100

In this example, no one physician owns more than 5 percent of the stock of Laboratory Corporation A and the total physician ownership is 15 percent. The commenter stated that these facts should allow the owner-physicians to refer to Laboratory Corporation A because, in the commenter's view, since the majority of stockholders are nonphysicians, the physicians have no incentive to overutilize laboratory testing to increase the value of their investments. The commenter concluded, therefore, that there would not be the risk of patient or program abuse.

Another commenter suggested that we create an exception for public companies similar to that of the safe harbor for investment interest under the anti-kickback statute. Generally, the commenter suggested that the exception should follow all of the requirements found in 42 CFR 1001.952(a), "Investment interests safe harbor."

Response: The second comment is related to the first, in that one of the requirements found in § 1001.952(a)