Comment: Another commenter wished to emphasize the requirement that, in order to qualify for the exception, the general public must have the same opportunity to buy and sell the entity's stock as physician-investors. As noted in the proposed rule, physicianpartners in a laboratory should not be permitted to exchange their partnership shares for stock in a new corporation, which is then publicly traded at some later date. The commenter was aware of one entity that has purchased physicianowned laboratories in just this manner. Therefore, the commenter believed that we should emphasize that such conduct is a clear violation of the regulation.

Response: The requirement at issue in the regulation was derived from section 1877(c), as it appeared prior to OBRA '93. Section 1877(c) used to require that investment securities be those which were purchased on terms generally available to the public. OBRA '93 amended this provision (the amendment is now retroactively effective as a result of SSA '94) to say that the investment securities are those which may be purchased on terms generally available to the public. We will interpret the amended provision and other provisions in OBRA '93 in a proposed rule covering all of the designated health services.

Comment: A few commenters indicated that they disagree with the proposed requirement that the \$100 million in assets must have been obtained in the normal course of business and not for the primary purpose of qualifying for this exception. The commenters believed there is no evidence that the Congress intended to deny protection to entities that meet the \$100 million asset test in part or in whole by acquiring assets for the purpose of qualifying for the exception spelled out explicitly in section 1877(c). The commenters suggested that the purchase of an independent clinical laboratory by a corporation intending to include the purchase in the total assets needed to qualify for this exception is not clearly an example of a corporation trying to circumvent the law through a sham transaction. One commenter went on to state that any corporation and physician involved in a good faith purchase and sale of a clinical laboratory in order to comply with the law would be unfairly penalized by the proposed language.

A few commenters urged that we eliminate the statement in the preamble advising the OIG to treat as a circumvention scheme any effort by an entity to obtain \$100 million principally for the purpose of meeting the "\$100 million in total assets" test.

Response: As mentioned in a previous response, we are withdrawing this interpretation and requiring that the corporation meet one of the following criteria: (1) it has, at the end of its most recent fiscal year or, on average during the previous 3 fiscal years, stockholder equity exceeding \$75 million or (2) until January 1, 1995, it had, at the end of its most recent fiscal year, total assets exceeding \$100 million, irrespective of how those assets were obtained.

The statement that the commenters have asked us to eliminate appears in the preamble to the proposed rule at 57 FR 8600 in the discussion on OIG regulations. Since we are not including a requirement about how the assets are obtained, we are not including language related to this issue in the final rule.

Comment: One commenter indicated that a major ambiguity appears in this exception when one considers how to treat physician investors who have acquired shares prior to the time the laboratory was publicly traded. As written, the statutory exemption might be interpreted not to protect such previously acquired shares since, by definition, they were not acquired in a transaction involving the general public.

The commenter requested that the final regulations specify that, once the laboratory meets both of the exemption's tests (that is, the stock exchange listing and the level of assets criteria), physicians who acquired their shares before this time be permitted to refer patients under certain conditions. That is, physicians can refer provided they own only shares with rights identical to those generally available to the public through trading on one of the specified exchanges.

Response: As we have pointed out in earlier responses, the requirement in the proposed regulation has been modified to reflect the statute, as amended by OBRA '93. OBRA '93 amended this provision (the amendment is now retroactively effective as the result of SSA '94) to say that the investment securities are those which may be purchased on terms generally available to the public.

Comment: One commenter requested that we use the same definition of public company that it believes is used by the Securities and Exchange Commission (SEC); that is, the definition used under General Accepted Accounting Principles. The commenter believed that use of this commonly accepted definition is in accord with the "public company" intent of the legislation and will maintain the "bright line" between referrals that can and cannot be influenced by ownership position.

Response: The American Institute of Certified Public Accountants, Inc., defines a public enterprise as a business enterprise—

• Whose debt or equity securities are traded in a public market on a domestic stock exchange or in the domestic overthe-counter market (including securities quoted only locally or regionally); or

• That is required to file financial statements with the SEC.

An enterprise is considered to be a public enterprise as soon as its financial statements are issued in preparation for the sale of any class of securities in a domestic market. (Commerce Clearing House, Professional Standards, AC Section 1072, 024(h).)

We do not believe that this definition adds any clarity to the very specific requirements found in the law; that is, for purposes of section 1877(c), a corporation is an entity that is listed for trading on the New York Stock Exchange or on the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis, or is a national market system security traded under an automated interdealer quotation system operated by the National Association of Securities Dealers.

Comment: One commenter suggested we allow the use of a consolidated balance sheet to show that the \$100 million asset test is met.

Response: A consolidated balance sheet is used for financial reports for a group of affiliated corporations, eliminating intercorporation debts and profits and showing minority stockholders interest. It also is used when, under certain circumstances, multiple related entities must report balances in a combined fashion instead of separately.

Since the statute excepts investment interests in a corporation with a minimum amount of assets (or, under OBRA '93, stockholder equity), we do not believe it is appropriate to aggregate the assets of multiple corporations on a consolidated balance sheet.

In the preamble to the proposed rule (57 FR 8597), we stated that the \$100 million in assets requirement applies only to the corporate entity that furnished the clinical laboratory services, and it does not include assets of any related corporations. This statement is misleading in that it applies only when the stock ownership giving rise to the financial relationship is held in the corporate entity that furnishes clinical laboratory services; it is