should, in the commenter's opinion, be eliminated.

Additionally, the commenter believed that providing a broader exception for referrals by HMO, CMP, or HCPP staff physicians is consistent with the statutory exemptions for services furnished by these organizations. The HMO, CMP, or HCPP exception recognizes that managed care plans may properly organize and operate their own clinical laboratories in the interest of serving their patients efficiently and economically. Those organizations may require their physicians to refer certain clinical laboratory services for both enrolled members and fee-for-service patients to their affiliated laboratories.

Even HMOs, CMPs, and HCPPs that engage physicians to practice in facilities owned and operated by the HMO, CMP, or HCPP may furnish services to Medicare beneficiaries who are not enrolled as members. Often this occurs when a patient "walks in" to the HMO, CMP, or HCPP clinic or when a relative accompanies a person who is enrolled in the plan.

The commenter believed that no purpose would be served by requiring physicians in HMOs, CMPs, or HCPPs that operate clinical laboratories to refer services for Medicare beneficiaries who are not enrollees to another laboratory. The commenter stated that these nonenrollee patients should be entitled to expect the same level of care as enrollees.

Response: As we have noted earlier, OBRA '93 added to the list of prepaid plans in the section 1877(b)(3)exception an organization that is a qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act). The statute specifically excepts from the physician referral prohibition only services furnished by the listed organizations to their enrollees. Our proposed and final regulation reflect this statutory limitation. We decline to add services furnished to non-enrollees as an additional exception under section 1877(b)(4). When HMOs, CMPs, and HCPPs are reimbursed by Medicare on a fee-for-service basis, we believe that there still exists an incentive for these organizations to overutilize services. The Secretary cannot create an additional exception unless she determines that there is no risk of patient or program abuse.

However, physicians who are employed by HMOs, CMPs, and HCPPs may still be able to refer non-enrolled patients to the laboratories that are affiliated with these organizations under other exceptions in the statute. For example, if the physicians only receive compensation from these organizations under an employment agreement or personal services contract, they can refer to the organizations' laboratory if they meet the requirements in section 1877(e)(2) or (e)(3).

F. Exceptions to Referral Prohibitions Related to Ownership or Investment Interest

1. Publicly-Traded Securities

In proposed § 411.357(a), we provided that physicians who hold an ownership or investment interest in certain entities may make referrals to those entities if the following requirements are met:

• The physician purchased ownership of the entity in the form of investment securities (including shares or bonds, debentures, notes or other debt instruments) on terms generally available to the public.

• The ownership or investment interest is in a corporation that meets the following conditions:

+ It is either listed for trading on the New York Stock Exchange or the American Stock Exchange or is a national market system security traded under an automated interdealer quotation system operated by the National Association of Securities Dealers.

+ It had, at the end of its most recent fiscal year, total assets exceeding \$100 million. These assets must have been obtained in the normal course of business and not for the primary purpose of qualifying for this exception.

As we have discussed elsewhere, OBRA '93 modified section 1877(c) in several ways. First, investment securities no longer have to be those purchased on terms generally available to the public; they must only be those which "may be purchased" on terms generally available to the public. Second, the securities can be those listed on additional exchanges. Third, the investment securities no longer have to be in a corporation with \$100 million in total assets at the end of a fiscal year; now the holdings of the corporation must be measured in terms of "stockholder equity," and the amount has been modified from \$100 million to \$75 million. This amount can now either be measured at the end of the most recent fiscal year or be based on the corporation's average during the previous 3 fiscal years. Finally, OBRA '93 extends the exception to apply to certain mutual funds.

Under the effective date provisions of OBRA '93, the amended version of section 1877(c) was not effective until January 1, 1995. SSA '94 revised this effective date provision to make the amended version of section 1877(c) effective retroactively to January 1, 1992; however, the revised effective date provision states that, prior to January 1, 1995, the amended § 1877(c) does not apply to any securities of a corporation that meets the requirements of § 1877(c)(2) as they appeared prior to OBRA '93. Section 1877(c)(2), prior to OBRA '93, contained the requirement that a corporation have \$100 million in total assets.

Comment: One commenter supported our proposed requirements. The commenter believed that the additional requirement concerning the purpose in obtaining assets will help eliminate certain obvious sham transactions that followed the passage of section 1877. The commenter suggested the inclusion of additional language requiring that these entities have \$50 million in shareholder equity. Such a threshold, according to the commenter, could help to ensure that the company has actual, hard assets, rather than simply "phantom" assets that are offset by significant liabilities.

Response: After consideration of the comments we received on this issue (see below), we have decided that it would be extremely difficult to prove exactly what a corporation intended when it decided to acquire assets; that is, to sort through a corporation's financial records to try to separate business purposes from nonbusiness purposes. We further believe that it would be difficult to define what is meant by "acquiring assets during the normal course of business." Therefore this final rule does not specify that the assets must have been obtained in the normal course of business and not for the primary purpose of qualifying for the exception.

We agree that the commenter's suggestion for "shareholder equity" is a good one, but we do not believe that the Congress meant to refer to this concept when it included the term "total assets" in the statute. That is so because the **OBRA** '93 amendments specifically replaced the concept of "total assets" with "stockholder equity," a change the legislative history describes as a modification of the law and not a clarification or explicit expression of what was already implicitly present in the law. Also, the fact that SSA '94 appears to make the \$100 million-totalasset-standard and the \$75 millionstockholder-equity- standard apply simultaneously until January 1, 1995 suggests that they are two different concepts. Beginning on January 1, 1995, the "stockholder equity" standard will prevail.