to be met for purposes of coverage or for purposes of application of the in-office ancillary services exception.

Furthermore, we note that section 1877(e)(8)(B) provides an exception for physicians who contract with an entity outside of their office for items or services, providing the items or services are furnished at a price that is consistent with fair market value. Fair market value is defined in section 1877(h)(3) as meaning the value in arm's-length transactions, consistent with the general market value.

We believe this exception permits a physician to contract with a laboratory outside of his or her office for certain services and to continue to refer testing to that laboratory, providing the services meet the requirements for fair market value. Therefore, an independent laboratory entity will be able to provide personnel to assist a physician in carrying out the CLIA requirements.

Accordingly, from the circumstances described by the commenter, the following conclusions emerge:

• In order to comply with the CLIA requirements, a physician or group practice may contract with a laboratory for the services of various physicians or other personnel. In these cases, as long as the direct supervision requirement is met, application of the in-office ancillary services exception is not jeopardized by the fact that the personnel performing the CLIA-related activities are not employed by the physician or group practice.

• Physicians' referrals to the laboratory with which they contract for the performance of CLIA-related activities will not be prohibited if the contract meets the "fair market value" requirement of the exception found in section 1877(e)(8)(B).

e. Location

Comment: One commenter believed the location requirements of the inoffice ancillary services exception arbitrarily distinguish between group practices and solo practitioners. The commenter stated that a referring solo physician, as well as a group practice, should be able to qualify under this exception if the laboratory is located in a building used for centrally furnishing clinical laboratory services. The commenter believed there is no remedial purpose served by requiring that a laboratory with which a solo practitioner has a financial relationship be in the same building as his practice, while permitting a laboratory with which a group practice has a financial relationship to situate the laboratory in a separate building.

Response: We believe that, in creating the exception in section 1877(b)(2) and entitling it "in-office ancillary services," the Congress meant to except situations in which a physician refers patients to the practice's own laboratory located in the physician's practice office, or nearby. As a result, the statute requires that the services be furnished in a building in which the referring physician furnishes physician's services unrelated to clinical laboratory services.

Congress, however, has apparently always regarded the same building requirement as too restrictive for a group practice. Before the enactment of OBRA '93, section 1877(b)(2)(A)(ii)(II) allowed a group practice to refer to a laboratory in another building that was used by the group practice for the centralized provision of the group's clinical laboratory services. OBRA '93 liberalized this provision even more, amending it to allow a group practice to refer to another building that is used for some or all of the group's clinical laboratory services, no longer requiring that the services be performed in a "centralized" laboratory. This provision is effective retroactively to January 1, 1992.

Because group practices can have practice offices in many locations, the Congress appears to believe that it could be difficult to locate the group's laboratory close to all of them. The legislative history for the OBRA '93 amendment points out that a number of group practices own and operate satellite facilities in communities other than the community in which the main clinic facility is located. (H.R. Rep. No. 111, 103d Cong., 1st Sess. 545 (1993))

We have not created an exception under section 1877(b)(4) for solo practitioners who refer to laboratories that are located in buildings other than the ones in which they practice. That is so because we believe the services would cease to be in-office ancillary services if they are referred to an outside location and the solo practitioner might be less likely to directly supervise the services. Also, we have seen no evidence that such an exception would be free from any risk of patient or program abuse.

3. Prepaid Health Plan Enrollees

Under § 411.355(c) of the proposed rule, the prohibition on referrals does not apply to services furnished by one of the following organizations to its enrollees:

• An HMO or a CMP that has a contract with us under section 1876 and 42 CFR part 417, subpart C.

• A health care prepayment plan that has an agreement with us under section

1833(a)(1)(A) and 42 CFR part 417, subpart D.

• An organization that is receiving payments on a prepaid basis for enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b– 1 note).

OBRA '93 amended section 1877(b)(3) to also include services furnished by a qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act) to an individual enrolled with the organization.

Comment: One commenter indicated that the HMO exemption appears to be available only for a narrowly defined group of HMOs. The commenter recommended broadening this exemption because HMOs employ utilization review criteria and these criteria serve as a disincentive to overutilize services.

Response: As mentioned above, OBRA '93 provided an exception for referrals to qualified HMOs for the provision of services to enrollees of the HMO. This exception would apply to referrals for Medicare beneficiaries to Federally-qualified health maintenance organizations (FQHMOs) without requiring the FQHMO to enter into a contract under section 1833 or 1876.

Comment: One commenter indicated that the final regulation should permit staff physicians of a Medicarecontracting HMO or competitive medical plan (CMP), or a health care prepayment plan (HCPP) operated under an agreement with HCFA, to refer Medicare beneficiaries to their affiliated clinical laboratories, regardless of whether the beneficiary is enrolled as a member of the HMO/CMP/HCPP.

This commenter presents the case of an entity that contracts with us to furnish covered services to Medicare beneficiaries as an HCPP under section 1833(a)(1)(A). Medical services furnished by the HCPP are predominantly provided at clinic locations by employee and independent contractor physicians. The commenter believed that the proposed regulation would require the clinics to establish two different protocols for their laboratory services: one for their HCPP enrollees and one for Medicare eligible patients who are not enrolled as members of the HCPP, and on whose behalf Medicare pays on a fee-forservice basis ("fee-for-service patients"). The commenter believed this distinction is artificial and could result in different levels of care for certain classes of Medicare beneficiaries. The distinction