unrelated to vision care in that area will not be exempt from the "substantially all" calculation. There appears to be no justification to exempt such group practices from the "substantially all" calculation in these cases, since there may not be a shortage for such services.

Our second change to the "substantially all" criteria involves group practices located outside an HPSA, but whose members provide services in an HPSA. These outside group practices must continue to meet the "substantially all" test, even if their members provide services in an HPSA. However, we are excluding from the 'substantially all" calculation for those groups outside an HPSA any time spent by group members providing the appropriate services in a particular type of HPSA (as described above), whether that time in the HPSA is spent in a group practice, clinic, or an office setting. We have amended § 411.351 ("Definitions") to reflect these concepts. We have also included a definition of "HPSA" in that section.

## 8. Ambulatory Surgical Center Exception

Comment: One commenter indicated that the Secretary should provide an exception for laboratory services performed in an ambulatory surgical center (ASC). Specifically, the exception should be provided if—

• Any ownership interest of the physician is in the ASC as a whole; and

 Any compensation relationship of the physician with the ASC does not relate to the provision of clinical laboratory services.

Response: We do not entirely agree with this comment. ASC facility services are services that are furnished by an ASC in connection with a covered surgical procedure and that would otherwise be covered if furnished on an inpatient or outpatient basis in a hospital in connection with that procedure. Medicare regulations at § 416.61 describe the scope of facility services. Generally, clinical laboratory services are not considered to be facility services. That is because, under § 416.61(b), ASC facility services do not include items and services for which payment may be made under other provisions in 42 CFR part 405, such as physicians' services, laboratory services, and x-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure). As a result, there are a limited number of diagnostic laboratory tests that are considered ASC facility services and which are included in the ASC rate. We agree with the commenter that referrals for laboratory tests that are performed in an ASC and included in the ASC rate should be excepted because there is no incentive to overutilize these services.

On the other hand, some ASC's have onsite laboratories that perform and bill for other laboratory testing furnished to ASC patients. Before enactment of CLIA, these laboratories were certified as "independent laboratories" and billed Medicare directly for their services. These laboratory facilities are now required to be certified under CLIA and continue to bill the Medicare program for the laboratory testing performed on the ASC premises, since general laboratory testing is not considered to be part of the ASC facility rate. We believe that, if the onsite laboratory facility is owned or operated by the ASC, referrals to the laboratory for general laboratory testing by a physician who has a financial relationship with the ASC should be prohibited, unless another statutory exception applies.

## 9. Home Care and Hospice Exception

Comment: One commenter indicated that home health agencies (HHAs) and hospices receive referrals from physicians to provide an array of services in the home. Currently, HHAs and hospices do not bill the Medicare program separately for laboratory services; instead, they bill for a home visit or the per diem hospice charge. The commenter made the following two recommendations:

- The regulations should clearly state that the prohibition does not apply to referrals to entities that do not bill Medicare separately for laboratory testing.
- Another exception should be developed to specify that the Medicare rules governing physician interest in HHAs would also apply to those entities in relation to laboratory services ordered by physicians. Thus, a physician's interest in a clinical laboratory would be permitted if the interest is less than 5 percent.

Response: As discussed earlier, OBRA '93 expanded the list of services subject to the prohibition to include 10 additional services. Because the list of services subject to the prohibition includes home health services, we do not believe an exception for laboratory services provided by home health agencies is warranted.

We agree with the commenter that referrals for laboratory tests that are performed by a hospice and are included in the per diem hospice charge should be excepted because a per diem amount does not reflect the number of tests performed. As a result, we are providing an exception in § 411.355 for laboratory services that are provided by

a hospice and billed as part of the per diem rate.

We disagree with the commenter's second recommendation. Section 1877 prohibits referrals to an entity by a physician who has a financial relationship with that entity. A financial relationship consists of an ownership or investment interest in the entity, regardless of the extent or degree of that ownership interest. Therefore, if a physician owns 5 percent or 95 percent of an entity, he or she is prohibited from making referrals to that entity, unless some exception applies. We will not grant an extra exception for ownership interests that are less than a particular percentage or that involve HHAs. That is because we do not have any evidence upon which to base a percentage or to ensure that the exception would be free from any risk of program or patient abuse.

## 10. Rural Laboratory Compensation Arrangements

Section 1877(d)(2) provides that ownership or investment by a physician in a rural provider of clinical laboratory services will not prohibit referrals by the physician to that rural provider.

Comment: One commenter stated that the statutory exception for rural laboratories is of little value since it provides only an exception to the ownership or investment interest test and still leaves the rural laboratory subject to the compensation arrangement test. Thus, the commenter recommended that the final rule contain an exception for compensation arrangements between a rural laboratory and a referring physician.

Response: Because of the OBRA '93 amendments to section 1877, we do not believe the exception recommended by the commenter is necessary. Section 1877 now contains exceptions that we believe will cover many compensation arrangements between physicians and laboratories. In addition to the section 1877(d)(2) ownership exception for rural laboratories, section 1877(e)(2) provides an exception if a laboratory compensates a physician as the result of a bona fide employment relationship, and section 1877(e)(3) provides an exception for remuneration from an entity to a physician under a personal services arrangement between the physician and entity. Finally, there are other additional exceptions relating to various other compensation relationships that a physician might have with a laboratory. For example, under section 1877(e)(8), a physician can purchase clinical laboratory services from a laboratory, or other items and services from a laboratory at fair market