If the physicians in the plan are directly employed by the academic center, then their referrals should not be prohibited if the employment meets the standards in section 1877(e)(2) and § 411.357(c). If, alternatively, the physicians or group practice members provide services to the academic center under contract, the personal services provided by these physicians would not be compensation if the arrangement meets the requirements in section 1877(e)(3) and § 411.357(d). In short, we cannot see why a separate exception would be necessary.

Comment: One commenter indicated that, in general, faculty practice plans fall under one of three organizational structures, as explained below:

- A single entity: Many faculty practice plans are organized as a single legal entity that submits a single bill for all physician services across specialties using one common Medicare provider number and, thus, clearly meeting the statutory billing requirement for a group practice.
- Multiple entities by specialty, each billing by its own group provider number: Other faculty practice plans within medical schools and teaching hospitals are organized as multiple legal entities, usually professional corporations established by specialty, that submit multiple bills using a provider number for the respective specialty group.

• Multiple entities by specialty, billing by individual physician provider numbers: Still other faculty practice plans are organized by groups but will submit multiple bills for service by specialty, using individual physician provider numbers.

The commenter recommended, therefore, that the final regulations recognize that a variety of faculty practice plan structures associated with a medical school or teaching hospital exist and should be able to qualify for the in-office ancillary services exception at the level of the umbrella organization. The commenter recommended that we not apply the criteria separately to each legal entity within the same academic setting.

Within an academic setting, according to another commenter, physicians may receive compensation from a variety of entities. They may order their laboratory work from one or more of these entities, such as a teaching hospital, a research laboratory for highly specialized testing, or in-office laboratories within faculty departments. Since there are often indirect financial relationships between and among the various entities within an academic setting, the law appears to prohibit referrals by faculty physicians

between and among these entities. The research laboratory may provide a unique situation because, as the commenter pointed out, it generally performs a highly specialized range of laboratory tests that are not available elsewhere. Therefore, the commenter urged us to craft an exception in the final rule that allows these and similar nonabusive arrangements to continue in the academic setting.

Response: We believe that as long as the faculty practice physicians receive remuneration from the academic institution for their bona fide employment or under personal service arrangements that meet the criteria in sections 1877(e)(2) and (e)(3), the physicians should not be prohibited from making referrals to laboratories that are owned by the academic institution.

7. Special Exception for Group Practices

Comment: We stated in our proposed rule that within the definition of "group practice" substantially all (at least 85 percent) of the patient care services of group practice physicians must be furnished through the group and be billed in the name of the group. Further, amounts received for those services must be treated as receipts of the group. One commenter stated that there are situations in which group practices will be unable to meet the "substantially all" requirements of section 1877(h)(4), or whatever percentage of patient care services is adopted in the final regulations. The commenter offered the example of 15 independently practicing physicians who have primary offices in one part of a city and establish a group practice clinic in a medically underserved area in the same city. Each physician spends 1 day a week at the clinic. In this case, only 20 percent of the services of the physicians in the group would be furnished through the group. This would be insufficient to meet the requirement of proposed § 411.351 that at least 85 percent of the aggregate services furnished by all physician members be furnished through the group practice.

The commenter recommended that an exception be added to the regulations that would allow group practices in medically underserved urban areas to furnish clinical laboratory services without being required to meet the "substantially all" requirement. In this commenter's view, this exception would tend to increase the availability of medical care in those urban areas currently deprived of adequate medical services without creating patient or program abuse.

Response: We note that the Congress has determined that there is a shortage of adequate medical care in locations designated as health professional shortage areas (HPSAs) under section 332(a)(1)(A) of the Public Health Service Act. In order to avoid discouraging group practice physicians from providing services in HPSAs, we are redefining the "substantially all" criteria in the definition of a group practice in § 411.351 in two ways. First, we are excluding from the "substantially all" test group practices that are located only in certain HPSAs. We have defined the term HPSA in reference to the definition of the term under the Public Health Service Act. Section 332(a)(1)(A) of the Public Health Service Act defines the term HPSA to include so-called "geographic HPSAs," that is, "an area in an urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services) which the Secretary determines has a health manpower shortage and which is not reasonably accessible to an adequately served area.

The Secretary has established criteria for designating areas having shortages of a number of types of health professionals, including primary medical care (which includes general or family practice, general internal medicine, pediatrics and OB/GYN), dental, mental health, vision care, podiatric, and pharmacy professionals. For purposes of this regulation, if an area is a primary care HPSA, any group practice located solely in that HPSA (regardless of whether it provides services of the type classified as primary medical care) will be exempt from the "substantially all" test. Since HPSAs do not exist for a number of specialty areas (for example, oncology, dermatology, neurology), if an area is a primary medical care HPSA, we believe that it is likely that there is a shortage of other types of professionals. Therefore, any group practices that are located solely in such an area and provide services of any type will be exempt from the substantially all" calculation.

In addition, if an area has been designated an HPSA for one of the other types of professional services, such as vision care, any group practice located solely in the HPSA and providing services that are of the type related to the HPSA designation, such as ophthalmology services, will be exempt from the "substantially all" calculation. On the other hand, if an area is an HPSA for vision care professionals (and for no other type of professional services), group practices providing services