

furnished by a group must be entered into by the group and must apply to all services that the physicians furnish as members of the group.

d. Structure of a Group Practice

Comment: One commenter stated that the definition of "group practice" applies not only to professional corporations and other single entities but also to "similar associations." The commenter believed that, when a group practice is organized into two separate entities that are organizationally interrelated through common ownership, administration, or similar substantial and ongoing connections (more than merely their joint ownership of a clinical laboratory), the two entities together should qualify as a similar association under the statute, thus allowing the two entities to satisfy the group practice criteria in the aggregate.

The commenter believed that if such entities are not aggregated for purposes of the group practice definition, then the primary care entity that has the laboratory must qualify separately as a group practice. Further, under the group practice definition, as set forth in the proposed rule, this may be impossible. The commenter described a situation involving a primary care entity and a specialty care entity. These two entities share certain office space, facilities, equipment, and personnel that physicians practicing in both entities jointly use. Thus, as stated by the commenter, there are two group practices sharing a laboratory facility. The commenter believed that each physician member of these entities does furnish the full range of his or her services through the joint use of space, facilities, equipment, and personnel, and the entities allocate the costs of this use on a formulaic basis. The commenter believed the organizational structure described in this situation should meet the conditions in the statute. The commenter pointed out that the preamble to the proposed rule states that each member of the group must individually furnish substantially the full range of services he or she routinely furnishes *through the group practice*. The commenter argued that this language is contradictory to the statute, which requires that each physician who is a member furnish the full range of services *through the joint use of shared space*, etc.—not furnish the full range through the group practice. The commenter suggested that the final rule state the actual requirements.

Response: It appears to us that what the commenter is describing is a situation in which two interrelated group practices share a laboratory. The

physicians' services exception under section 1877(b)(1) allows members of the same group practice to refer Medicare patients to each other for clinical laboratory services, as long as one of the physicians either personally performs the services or personally supervises the provision of the services. Thus, section 1877(b)(1) clearly contemplates physicians *within the same* group practice, but not physicians in different group practices. The in-office ancillary exception in section 1877(b)(2) allows members of the same group practice to refer to each other as long as the physician providing or supervising the services meets the tests in section 1877(b)(2) (A) and (B) for personal performance or direct supervision, location, and billing.

To qualify for the in-office ancillary services exception, an organization of physicians must meet the definition of a "group practice" under section 1877(h)(4). Under the definition, a group practice "means a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association." We agree that, in including a "similar association" in the list, the Congress has provided some flexibility for different kinds of entities to qualify as group practices. Nonetheless, we also believe that the statutory definition clearly contemplates only single legal entities. We do not view two independent group practices as a single practice, just because they are organizationally interrelated through common ownership or other substantial and ongoing connections.

We believe that the statute would have explicitly allowed for a "common ownership" or "substantial connection" configuration as part of the group practice definition had the Congress intended to include it. Also, it appears to us that using the premise of common ownership or substantial connection to combine individuals and entities could lead to far-reaching exceptions to the referral prohibition that we do not believe the Congress ever intended. For example, two solo practitioners could state that they are interrelated through shared administrative services and their common ownership of a shared laboratory, thus qualifying them as a similar association.

As we explain throughout this preamble, we do not believe that a clinical laboratory that is shared by associations of physicians who do not meet the definition of a single group practice will generally qualify for the in-office ancillary services exception. However, each individual physician in

these groups might qualify separately for the exception by meeting the requirements in section 1877(b)(2). That is, the physician must personally furnish the services or directly supervise the individual(s) that are furnishing the services. Further, the services must be furnished in a building in which the referring physician furnishes physicians' services unrelated to clinical laboratory services, and the services must be billed by the physician or an entity wholly owned by the physician.

Comment: One commenter indicated that we should address the issue of group practices that may include more than one legal entity as long as the entities either are in parent-subsidiary relationships or are under common ownership and control. The commenter stated that the proposed definition of group practice requires an entity to be legally organized, and gives multiple examples of the types of legal entities typically used in group practices. The commenter believed the definition is silent on the question of whether a group practice may have more than one such legal entity under a common umbrella. For example, a "parent" professional corporation or partnership might own subsidiary entities for real estate and/or equipment ownership or for billing or ancillary services. Alternatively, rather than having a parent/subsidiary relationship, these same types of separate entities might operate jointly under the common ownership and control of a core group of physicians. These separate structures have been highly desirable for reasons related to taxation, benefits, liability, debt service capacity, etc.

Response: This commenter was concerned about groups of physicians who furnish services through a "group practice" that is composed of several legal entities. The commenter believed that such a group practice should be able to take advantage of the in-office ancillary services exception as long as the entities are in either parent-subsidiary relationships or are under common ownership and control. The commenter specifically mentioned examples in which a professional corporation might own subsidiaries for providing equipment, for billing, or for ancillary services.

The definition of "group practice" in section 1877(h)(4)(A) means a group of 2 or more physicians, legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association. As we have said elsewhere in this preamble, we believe that the statute contemplates a group