practice that is composed of one single group of physicians who are organized into one legal entity. In short, we do not believe that a group practice can consist of two or more groups of physicians, each organized as separate legal entities.

However, we do not believe the statute precludes a single group practice (that is, one single group of physicians) from owning other legal entities for the purpose of providing services to the group practice. Thus, a group practice could wholly own a separately incorporated laboratory facility which provides laboratory services to group practice or other patients. However, because the group practice physicians have an ownership interest in the laboratory, they could be prohibited from referring to the laboratory, unless an exception applies.

The physicians could qualify for the in-office ancillary services exception, provided they meet the requirements for supervision, location, and billing. This exception does not appear to dictate any particular ownership arrangements between group practice physicians and the laboratory in which the services are provided. In fact, the billing requirement in section 1877(b)(2)(B) allows the services to be billed by the referring physician, the group practice, or an entity wholly owned by the group practice. The exception appears to anticipate that a "group practice," as defined in section 1877(h)(4), may wholly own separate legal entities for billing or for providing ancillary services.

e. Corporate Practice of Medicine

Comment: Two commenters indicated that there are legitimate physician group practice structures and relationships that may not satisfy the definition of a group practice as set forth in the proposed rule. A specific concern is with group practice organizations affiliated with hospitals that are organized in compliance with State corporate practice of medicine statutes.

In States that have these statutes, according to the commenters, only a validly-organized professional corporation or professional association can enter into employment arrangements with physicians.

One of the commenters presented an example of a group practice that is organized as a nonprofit hospital affiliated corporation that owns a clinical laboratory. The nonprofit hospital-affiliated corporation will be unable to employ the physicians; that is, a separate professional corporation must be established to employ the physicians in accordance with applicable State law. Typically, this commenter claimed,

nonprofit corporations will not qualify as the appropriate vehicle for a for-profit professional corporation or association.

The commenters believed that entities such as those described above (joint not for profit/for profit structures) that meet certain specific standards should qualify under the "similar association" language of the group practice definition. They believed that, so long as all other requirements established by the Secretary relating to appropriate standards for group practices (including the performance of services, billing practices, location of facilities, and income distribution provisions) are met, these entities do not pose a threat of abuse to the Medicare program and, as a result, they should be considered as a single group practice under the definition. To ensure that only appropriate entities qualify, one commenter suggested that (1) the separate professional corporation be organized for the sole purpose of providing medical services to the nonprofit corporation/group practice and be obligated to furnish those services exclusively to the nonprofit corporation, and (2) that the nonprofit corporation perform all other services associated with a group practice (including laboratory, billing, etc.) and employ all nonphysician staff.

Response: We believe the commenters are asking that we regard a joint structure, such as a nonprofit hospital-affiliated corporation linked with a professional corporation or association, as one group practice. This designation would allow the physicians in the professional corporation or association to refer to the nonprofit corporation's laboratory under the physicians' services or in-office ancillary services exceptions in section 1877(b).

In order to meet the definition of a group practice, there must be one identifiable legal entity. As we understand it, the clinical laboratory is owned by a nonprofit hospital-affiliated corporation but, because of the corporate practice of medicine requirements, that nonprofit corporation is unable to directly employ the physicians. As a result, the physicians are members of a separate professional corporation or association. The hospitalaffiliated corporation and the professional corporation or association are separate legal entities that cannot qualify as one group practice. Also, because the hospital-affiliated corporation cannot directly employ the physicians, the exception in section 1877(e)(2) does not apply. (This exception allows referrals by a physician when there is a compensation arrangement between an entity and a

physician for the employment of the physician.)

We see one possible exception for a nonprofit corporation that is affiliated with physicians who perform certain physician services. Under section 1877(e)(3), as amended by OBRA '93, there is an exception from the prohibition on physician referrals in the case of a personal service arrangement involving remuneration from an entity to a physician, or to an immediate family member of a physician, providing—

• The arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement;

• The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity:

• The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;

• The term of the arrangement is for at least 1 year;

• The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;

• The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law; and

• The arrangement meets any other requirements the Secretary imposes by regulation to protect against Medicare program or patient abuse.

If the nonprofit corporation (that owns the laboratory) and the professional corporation or association (that has physician investors) have such an arrangement, the physicians would not be prohibited from referring laboratory testing to the nonprofit corporation's laboratory.

f. Not-For-Profit Corporations

Comment: One commenter asked about the provision that permits group practices to be legally organized as not-for-profit corporations. The proposed rule defines a "group practice" as "a group of two or more physicians legally organized as * * * a not-for-profit corporation * * *." The commenter, however, stated that not all group practices organized as not-for-profit groups have physicians as their original incorporators or corporate members, nor