is this required by State law. As an example, the commenter stated that taxexempt hospitals often have affiliated group practices, and the group practice's operating entity (to which the commenter referred as a "physiciandirected clinic") might be a not-forprofit corporation separate from the taxexempt hospital entity that employs the physicians. This arrangement does not present a potential for abuse, in the commenter's view, although it is unclear whether a not-for-profit physician-directed clinic organization affiliated with a not-for-profit hospital in this manner meets the definition of a group practice. Therefore, the commenter recommended that the final regulation recognize the arrangements.

Response: As we understand the commenter's example, a tax-exempt hospital employs physicians who are part of an affiliated not-for-profit physician-directed clinic that was originally organized by the hospital. (Under Medicare, a physician-directed clinic is one in which (1) a physician (or a number of physicians) is present to perform medical (rather than administrative) services at all times the clinic is open; (2) each patient is under the care of a clinic physician; and (3) the nonphysician services are under medical supervision. (See Medicare Carriers Manual, section 2050.4.)) Further, we understand the commenter to be making the following suggestions:

• That an entity attempting to qualify as a group practice need not have been organized (or incorporated) by physicians; that is, as long as the entity is one in which two or more physicians have been brought together as a group practice, it does not matter that the initial organizing was done by nonphysicians.

 That an entity that, in fact, is a physician-directed clinic, organized by an affiliated hospital, be permitted to qualify as a group practice.

As to the first suggestion, the commenter referred to only the regulations, but the definition of "group practice" at section 1877(h)(4) also requires that there be "two or more physicians legally organized" as a notfor-profit corporation or as one of several other specified associations. Because the statute is silent about who must actually legally organize the association or operate or control it, we believe that any individuals or entities can assume these tasks, as long as the group practice meets all of the other specific requirements in section 1877(h)(4). Thus, if a clinic (or other facility) is legally organized to include two or more physicians and provides the services of physicians, it is a group

practice, even if it is established, operated, and controlled by a nonphysician group or corporation. This would be so regardless of who employs the physicians (in the scenario presented by the commenter, the clinic physicians were employed by the hospital that established the clinic).

g. Individual Pathology Services

Comment: One commenter suggested that the proposed regulations may preclude arrangements under which a group practice retains the services of an independent pathologist to direct the group's laboratory or otherwise assist in improving the quality of laboratory services available. The commenter wrote that the group practice may not be able to satisfy the definition of a group practice laboratory for purposes of section 1877(b)(2) if it retains the services of an independent pathologist who is not considered a member of the group, but who provides medical direction to the laboratory. Second, according to the commenter, an independent pathologist affiliated with a reference laboratory may be unwilling to provide consulting services to a group practice laboratory unless the consulting arrangement is specifically excepted by the regulations. Therefore, the commenter requested that the final regulations provide that (1) a pathologist retained by a group practice on a regular, part-time basis to direct, supervise, and otherwise assist in the performance of laboratory services be considered to be a member of the group practice; and (2) the services of a pathologist serving as a laboratory consultant be included within the category of exceptions set forth in proposed Section 411.359(e)(1)(i) (that is, service arrangements with nonhospital entities).

Another commenter requested that we develop an additional exception relating to compensation arrangements involving the provision of consulting services, as opposed to the furnishing of actual testing services. The commenter suggested that the arrangement would have to be: in writing, consistent with fair market value for the consulting services provided, and not conditioned on referral of laboratory services from one party to the other or otherwise related to the volume or value of referrals for laboratory services.

Response: First, part-time or contract physicians, including independent pathologists, may be considered members of a group practice if they meet the conditions in the "member" definition in § 411.351. As indicated by the commenter, a group practice can hire a pathologist to direct, supervise, or

otherwise assist in performing laboratory tests. We agree that this is an important point because the most significant advantage of a practice meeting the group practice definition is that it qualifies the group for the inoffice ancillary services exception in section 1877(b)(2). This exception applies if the referring physician or another member of the same group practice either performs or directly supervises the performance of the laboratory services. A group practice would not be able to use the section 1877(b)(2) in-office exception if it is a group practice member who is referring patients to the group's laboratory, but it is a nonmember pathologist who is performing or supervising the laboratory services.

The second concern of the first commenter involves an independent pathologist, who is somehow "affiliated" with an outside laboratory, who might be unwilling to provide consultation services to a group practice laboratory unless the consulting arrangement is specifically excepted from the prohibition by the regulations. Following is our analysis of such a situation.

First, the group practice laboratory is itself a laboratory entity that is compensating a pathologist (physician) for certain services the physician is providing and that relate to the group's laboratory services. We believe the pathologist could refer to the group practice laboratory if this arrangement fits within the exception in section 1877(e)(3). Section 1877(e)(3) excepts from the term "compensation arrangement" payments from an entity to a physician for personal services provided by the physician under an arrangement. The arrangement must meet certain criteria (for example, the arrangement must list the specific services in writing, be signed, be reasonable and necessary, and compensation must be for fair market value).

Section 1877(e)(3) does not appear to differentiate between physicians receiving compensation on the basis of whether they are independent contractors who also service other outside laboratories or whether they are employees or owners of outside laboratories.

The group practice could also be regarded as a group of physicians who may be purchasing services from an outside laboratory (if the pathologist is employed by or owns the outside laboratory). If this is the case, the compensation could instead be excepted under section 1877(e)(8). This provision excepts payments *made by a physician*