exception, there is not sufficient basis in the rulemaking record to support an exception that meets the statutory standard. For that reason, we believe that Congress should provide further clarification or specific statutory authority in this area.

• The first suggestion made by the commenters was that a shared laboratory be limited to a fixed number of physicians. In our view, however, any attempt to select a number (three, five, ten, and so on) would be arbitrary. That is because we do not currently have data that would support making a distinction based on the number of physicians involved. We see no rational basis on which to establish or impose a limit.

• The second suggestion is to limit the exception to physicians who occupy the same office space or whose offices are contiguous in the same building. As explained in the response to the last comment, depending on how the physician's office space and the shared laboratory space are physically arranged, the in-office ancillary services exception provided in § 411.355(b) could apply. But we emphasize that the direct supervision and billing requirements must also be met.

With respect to the remaining points, even if considered cumulatively, they do not clearly describe a situation in which there could be no program or patient abuse. Physicians could still have the opportunity to overutilize services with the possibility of profit that is inherent in any ownership arrangement. We are not suggesting that all physicians who might wish to participate in shared laboratory arrangements would overutilize laboratory tests. We do not believe, however, that there is a basis for concluding that the arrangements pose no risk of patient or program abuse.

Comment: One commenter indicated that, if the Secretary establishes an exception for shared laboratories, physicians involved in shared laboratory arrangements could be required to attest in writing that they meet the criteria required by the Secretary. This requirement would be like the one in the proposed regulation requiring that physicians attest in writing to their Medicare carrier that they meet the group practice exception.

Response: To clarify one point, we required only one attestation in the proposed rule; that is, that a group practice attest in writing, to the appropriate Medicare carrier, that the group complied with the standard we proposed to use to determine whether substantially all of the patient care services of group member physicians are furnished through the group as was

required by section 1877(h)(4)(B) (now section 1877(h)(4)(A)(ii)). There are other standards that a group practice has to meet in order to qualify, but we did not propose that they be the subject of an attestation procedure.

In any case, as explained above, we do not believe that a separate exception for shared laboratories is justifiable.

Comment: One commenter suggested that multiple group practices within the same building be allowed to refer patients to one central laboratory that was created for the patients of the group practices.

Response: What is described here may be a laboratory owned by several group practices that does testing for patients of each group. In effect, the laboratory would be an independent entity that is shared by several group practices in the sense that it does business with each of its group practice owners. (A second possibility is that the laboratory is owned by one group to perform testing for its own patients but also accepts referrals from other groups or other outside sources. This latter situation is discussed elsewhere in this preamble.)

As we have explained in earlier responses to comments, we are not providing a general exception for shared laboratories such as the one described by the commenter. The physicians in the multiple group practices could refer to the laboratory, provided that each referral meets the requirements of the in-office ancillary services exception in section 1877(b)(2). This means that the services must be personally performed by or directly supervised by the referring physician or another member of that physician's own group practice and the services must be billed by the referring physician, the group practice, or an entity wholly owned by the group practice or referring physician.

There is no evidence from the commenter's description that the group physicians personally perform or directly supervise the laboratory services. Also, if this is the case, the group practices cannot individually bill for the services under section 1833(h)(5)(A), which generally allows payment only to the person or entity that performs or supervises the performance of clinical diagnostic laboratory tests. If the laboratory bills, the services will not meet the billing requirement in section 1877(b)(2).

2. Specialized Services Laboratory

Comment: One commenter requested an exception for referrals for "specialized services." This exception would permit the establishment of laboratories by groups of individual practitioners within a common area of expertise.

The exception would apply when there is a public health need for specialized clinical services not readily available in a geographic region.

According to the commenter, general laboratories may lack the equipment or the expertise to meaningfully analyze samples from patients suffering from particular diseases. The commenter stated that the cost of specialized services could be lowered by making them readily available to patients who would otherwise incur unnecessary costs and delays because samples have to be shipped to laboratories not reasonably close to them. The commenter stated, as an example, that laboratories that usually handle normal blood specimens typically fail to calibrate their laboratory equipment for renal patients who express blood values that depart significantly from the norm. In the commenter's view, the technicians at general laboratories tend to be inexpert at processing these abnormal samples. In turn, this causes dialysis patients to incur unnecessary expense and endure needless delays and incorrect test results. The commenter also stated that laboratories that are not expert in evaluating renal blood samples tend not to report patient values, including cumulative historical laboratory results, to dialysis clinics in the same detailed manner as laboratories that specialize in renal patients.

Response: As mentioned previously, a physician's Medicare referrals to a laboratory owned by that physician will not be prohibited if the laboratory is located in a rural area (as defined in new § 411.356(b)(1)). Therefore, physicians with an ownership interest in a specialized laboratory that is located in a rural area are not prohibited because of that investment from referring Medicare patients to the laboratory. We believe that it is likely to be in rural areas that specialized equipment or technical expertise would be in short supply.

Furthermore, we believe the CLIA certification that is now required for any laboratory that performs tests on human specimens will tend to induce those laboratories that fail to calibrate their equipment or operate in other ineffectual ways to improve their performance or risk going out of business. For example, under CLIA, laboratories are subject to proficiency testing and personnel requirements. Failure to comply with accepted standards can result in serious sanctions. Thus, we do not agree that a special exception is warranted because