but that a parallel exception was not included in § 411.355, the title of which is "General exceptions to referral prohibitions related to ownership and compensation." Instead, the commenters pointed out, the proposed rule contains separate exceptions, one for "ownership or investment interests" and one for "compensation arrangements." In the view of these commenters, these regulatory provisions are not consistent with section 1877(b)(4), and they recommended that the regulations be revised so that § 411.355 reflects the content of section 1877(b)(4).

Another commenter had several questions about proposed \$411.357(b)(3)(i) and what is meant by an ownership interest in a distinct part or department of a hospital. The commenter stated that most hospitals are incorporated entities, being either a for-profit or not-for-profit corporation and that parts or departments are assets of the incorporated entity and cannot be owned separately. This being the case, the commenter asked the following:

- How can a physician own an interest in a distinct part of a corporation or was the intention to refer to ownership of entities related to a hospital?
- Why should ownership in an entity related to a hospital cause referrals from a physician to be prohibited if the related entity is not a clinical laboratory (for example, a hospital owns 60 percent of a subsidiary that is not a clinical laboratory and the physician owns 40 percent).
- Why should the facts of this example result in a situation that is any more subject to abuse than one in which a physician has general ownership in the hospital and is authorized to perform patient care services at the hospital?

Response: The first set of commenters maintained that there was a conflict between the exception set forth in section 1877(b)(4) and the proposed regulatory exceptions. We believed that the combination of the provisions at  $\S 411.357(b)(3)(ii)$  of the proposed rule and § 411.359(g) of the proposed rule effectively incorporated the section 1877(b)(4) provision. We had considered including the content of these two regulatory provisions under one provision in § 411.355, as was suggested in the comment, but that section of the regulation addresses services that can qualify for an exception, whereas section 1877(b)(4) addresses financial relationships that can qualify. Since under section 1877(a) all financial relationships are either ownership/investment interests or

compensation arrangements, we included the section 1877(b)(4) exception under both § 411.357 (which applies to ownership/investment exceptions, and is now § 411.356) and § 411.359 (which applies to exceptions for compensation arrangements, and is now § 411.357).

We believe the commenters' dissatisfaction with our method for incorporating section 1877(b)(4) may stem from the way we drafted the provision in § 411.359(g). We now believe that this proposal deviates from the statute. We discuss this issue and our solution for it in our response to the next comment.

As a result of OBRA '93, as amended by SSA '94, the ownership/investment aspect of section 1877(b)(4) applies only until January 1, 1995. Some aspects of the compensation exception continue in effect, since OBRA '93 incorporated them into section 1877(e)(4).

The second comment asked, in regard to proposed § 411.357(b)(3)(i) and section 1877(d)(3), how a physician can own an interest in a distinct part of a corporation when hospitals are one incorporated entity. As we explained in an earlier response, we believe that a "hospital" can consist of any separate legally-organized operating entity plus a variety of subsidiary, related, or other entities if the hospital bills for the services furnished to its patients by those entities. In drafting section 1877(d)(3), Congress itself perceived that a hospital can consist of separately owned, subdivided parts and that a physician could own an interest in either the hospital itself or only in a subdivision. We are defining "hospital" for purposes of this regulation, to reflect this concept.

The commenter has also asked whether the intention of the exception in section 1877(d)(3) was to refer to ownership of entities related to a hospital. Although the statute does not explicitly say this, it does say that the exception will not apply if a physician's ownership interest is merely in a subdivision of the hospital, rather than in the hospital itself. We believe that a subdivision can be a related entity. We have interpreted such entities, in response to other comments, as parts of a hospital if the hospital bills for services furnished by these entities to hospital patients (excluding situations in which services are furnished for a hospital "under arrangements"). A physician with an interest in a joint or related entity would not have an ownership interest in the hospital at all if the hospital did not bill for the services furnished by the joint or related entity.

The commenter has also asked why ownership in a related entity should cause referrals from a physician to be prohibited if the entity is not a clinical laboratory (for example, if the hospital owns 60 percent of a non-laboratory entity and the physician owns 40 percent). If the entity in this situation is part of the hospital, any referrals by the physician to the hospital laboratory would not qualify for the exception in section 1877(d)(3). To qualify for this exception, the physician's ownership interest must be in the hospital itself and not in a subdivision. However, the physician's referrals could qualify for the exception in section 1877(b)(4)which, until January 1, 1995, excludes any ownership interest in a hospital, provided the ownership interest does not relate to the provision of clinical laboratory services.

Finally, the commenter has asked why the facts in the example should be more subject to abuse than one in which a physician has a general ownership in the hospital and is authorized to perform patient care services there. Section 1877(d)(3) specifically requires that, to take advantage of this exception, a physician must have an ownership interest in the hospital itself, and not in a subdivision. We must reflect this requirement in the regulation, and have incorporated it into the final rule at § 411.356(b)(3). We have not broadened this exception to apply to any other ownership interest in a hospital because we have seen no evidence that such an expanded exception would be free of the risk of program or patient abuse.

Comment: There were two comments relating specifically to proposed § 411.359, which contains exceptions for certain compensation arrangements. One commenter asked under what authority we had limited the broad exception in section 1877(b)(4). Under that exception, the commenter pointed out, any financial relationship with a hospital is excepted (ownership/ investment interest or compensation arrangement), as long as the relationship does not relate to the furnishing of clinical laboratory services. As such, the commenter questioned why this exception was not included under proposed § 411.355, which covers general exceptions that apply to both ownership/investment and compensation relationships. The commenter believed that, in covering section 1877(b)(4) under § 411.359(g), we had limited the exception so that it no longer constitutes the broad exception, for all financial relationships, included in the statute.

The commenter referred to the fact that the exception in § 411.359(g) is