

is not necessarily a means of providing them compensation. As an example, the commenter pointed out that in New York, a State that has long had a direct billing law and related regulations, discounts are passed directly on to the patient or insurance carrier. It is a market mechanism that, in the commenter's view, actually works to hold down the cost of health care. The commenter considered discounts a goal to be aimed for, not a practice to be precluded. The commenter indicated that a simple way to help hold down the cost of health care is to follow the direct billing practices established in New York or to exempt those States that already have such laws.

Response: This commenter made a good point. Nonetheless, the Medicare statute generally does not currently authorize us to impose the "direct billing" requirement found at section 1877(h)(5)(A) for laboratory services other than those furnished to Medicare patients. As we noted in an earlier response, we will address the discount issue in our proposed rule covering the designated health services.

Comment: A commenter stated that physician groups often contract with HMOs to provide medical care for HMO members and described the following situation: The physician group is paid a predetermined monthly rate per enrollee as payment in full for all outpatient medical services, including laboratory services furnished to covered enrollees. To ensure that the physician group can furnish all necessary services in an efficient and cost effective manner, the physician group typically enters into discount agreements with providers not affiliated with the group to furnish services to the HMO's patients at a discounted rate. These arrangements include laboratory services at a discounted rate.

In the commenter's view, this type of discount arrangement would not pose any risk of Medicare program or patient abuse under the following conditions:

1. The HMO does not bill the Medicare program for any Medicare patient laboratory tests performed by an outside laboratory.
2. The physician group does bill commercial insurance for tests performed but does not mark up the cost of the test; that is, the group bills the exact amount charged by the outside laboratory.
3. The discount arrangement is not, in any way, influenced by the volume of Medicare patient laboratory tests sent to the laboratory facility.
4. The discount arrangement is based upon the volume of laboratory services purchased for HMO patients.

5. An agreement to provide laboratory services to HMO patients at a specified fee or discount that is not based upon volume of Medicare referrals is revenue neutral as far as the Medicare program is concerned. In other words, the fixed discount or specified fee is established completely independently of the volume of Medicare referrals and certainly independently of the Medicare program itself.

Response: We believe that the exception set forth in sections 1877(b)(3) and section 411.355(c) applies in this situation, at least in part. Under those provisions, the prohibition on referrals does not apply to referrals for services furnished by an organization with a contract under section 1876 to an individual enrolled with the organization. (Also see 42 CFR part 417, subpart C.) This exception also applies to referrals for services furnished by organizations with health care prepayment plans that have agreements with us under section 1833(a)(1)(A) to an individual enrolled in the plan (see 42 CFR part 417, subpart D) and by organizations receiving payments on a prepaid basis for their enrollees in accordance with the terms of a demonstration project authorized under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1 note). Also, as added by OBRA '93, this exception applies to referrals for services furnished by a qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act) to its enrollees. Thus, the exception no longer requires that all HMO plans contract with Medicare in order to qualify for the exception. The exception in section 1877(b)(3) applies to all services furnished by the organizations listed in that provision, including those services furnished to enrollees by outside physician groups, which have contracted with the organizations. As we noted in earlier responses, we will address the issue of how to treat discounts under section 1877 in the proposed rule covering the designated health services.

b. Forgiveness of Debt; Other Benefits

Comment: One commenter indicated concerns with the inclusion of the term "forgiveness of debt" in the definition of remuneration. According to the commenter, there are a number of legitimate reasons why a laboratory might forgive a debt owed by a physician. For example, there might be a dispute over the correctness of a bill or over whether the physician had in

fact ordered certain tests. In such instances, a laboratory might decide to write off the debt. In contrast, the laboratory might decide to furnish services to a physician who had previously owed money to the laboratory, which the laboratory had written off. This same commenter recognized that forgiveness of debt in such a situation might be an abuse; that is, the laboratory might simply forgive an obligation owed in order to obtain continued referrals. Thus, the commenter agreed that the forgiveness of debt should be considered remuneration within the meaning of the statute, but added that the definition should distinguish between the atypical situation and routine types of write-offs.

One commenter believed that the inclusion of "other benefit" in the definition of remuneration is very broad. The commenter believed the definition could reach a variety of services that are integral to the provision of laboratory services and that enhance the quality of the services furnished. Examples of "other benefits" that might be exchanged between a physician and laboratory mentioned by the commenter are test tubes and other laboratory testing supplies, telecommunications equipment such as stand-alone printers, courier services, and educational or consultation services.

Another commenter recommended that the definition of remuneration be amended to exclude from the prohibited category those items or services that are enhancements to the quality of laboratory services and that have no value independent of the laboratory service, such as courier pickup of samples, increased frequency of pick up of samples, and electronic transmission of results.

One commenter recommended that the definition of remuneration be amended to exclude "discount, forgiveness of debt, or other benefit" and that we retain the statutory definition.

Response: Section 1877(h)(1) as amended by OBRA '93 specifies that a "compensation arrangement" does not include arrangements involving only the following kinds of remuneration:

- The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.
- The provision of items, devices, or supplies that are used solely as follows:
 - + To collect, transport, process, or store specimens for the entity providing the item, device, or supply.