PUBLICATION

OIG Nixes Arrangements Involving Free Tests [Ober|Kaler]

Authors: Robert E. Mazer
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Labs Attempt to Counter Exclusive Lab Arrangements

With increasing frequency, clinical laboratories have found themselves unable to receive any payments for tests performed for individuals whose third-party insurer required all tests to be referred to one or more designated laboratories (Exclusive Plan(s)). These Exclusive Plan arrangements included no provisions for out-of-network payments for laboratory tests. Laboratories that were not participants in the arrangement were unable to obtain any payments from the insurer for tests subject to the arrangements.

Under these circumstances, laboratories often feared that they may be shut out of all testing required by the medical practice, not just tests subject to the Exclusive Plan. The concern was that if physicians were required to refer some tests to particular laboratories under the Exclusive Plan, then they may send all testing to that laboratory as a matter of convenience. To reduce this possibility, some labs offered to perform tests for physicians' patients covered under an Exclusive Plan for free – without any charge to the patient, insurer or physician. That would make it more convenient for the medical practice to refer all of its tests to the laboratory. While the provision of free services can raise significant regulatory issues, this practice was generally considered to be permissible because it provided no financial benefit to the referring physician. This position was supported by the OIG's 1994 Special Fraud Alert on Arrangements for the Provision of Clinical Lab Services, which indicated that the waiver of charges under an Exclusive Plan would not implicate the Federal Antikickback Statute (FAS) unless the referring physician would receive a financial benefit under the practice's managed care contract. This might occur if the managed care plan offered a bonus or other payment to a physician if utilization of ancillary services was kept below a certain level.

Additionally, because the insurer would not receive any bill for the tests, the practice avoided some of the issues raised when only the patient's coinsurance or deductible was waived.

OIG Advisory Opinion

In OIG Advisory Opinion No. 15-04 (March 25, 2015), the OIG opined that an arrangement like that described above implicated potentially both the FAS and the prohibition against charging Medicare or state health care programs “substantially in excess” of the provider's or supplier's usual charge.

Federal Antikickback Statute

In this Advisory Opinion, the OIG stated that the main purpose of the provision of free testing services was “to secure all of the referrals, including services that would be rendered to federal health care program beneficiaries, from participating physician practices.” Therefore, it had to determine “whether any remuneration could flow to a source of referrals or recommendations.”

The OIG recognized that the physicians and physician practices would not receive any direct financial payment. The proposed arrangement would not be offered in circumstances where the physician practice draws the specimen in its office and/or bills a payer directly for the draw or testing. The OIG determined,

nevertheless, that the medical practice would potentially receive remuneration based on a combination of the facts presented. First, the OIG reasoned that the arrangement would be more convenient for the physician practice because it would receive all test results from a single laboratory and the practice would gain efficiency from maintaining a single interface with a single laboratory. Second, the OIG stated that the arrangement could relieve physician practices of monthly interface maintenance fees because the practice would need to maintain a single laboratory interface only. According to the OIG, while the interfaces themselves may be provided by laboratories without charge, the laboratory requesting the advisory opinion had stated that some electronic medical record vendors charged physician practices a monthly maintenance fee. On this basis, according to the OIG, it could not "rule out with sufficient confidence the possibility that, for particular agreements with physician practices, the [laboratory] would be offering remuneration to induce the referral of federal health care program beneficiaries. . . ." Notably, the OIG did not even mention its 1994 Special Fraud Alert, and raised for the first time in the context of the waiver of managed care charges the theory that remuneration may stem from the *convenience* associated with the medical practice's ability to maintain fewer interfaces.

Substantially in Excess

The Medicare statute permits exclusion of any person or entity that submits charges to Medicare or Medicaid that are substantially in excess of its usual charges. The OIG stated that, in the past, it had said that "a provider need not even worry about [this provision] unless it is discounting close to half of its non-Medicare or non-Medicaid business." This statement reflected the OIG's view that more limited discount practices would not affect the determination of the laboratory's "usual" charge. Under the proposed arrangement, subject to OIG review, the OIG stated that a substantial percentage of the laboratory's physician practice clients "have indicated that between 10 percent and 40 percent of their patients are enrollees of Exclusive Plans." Therefore, according to the OIG, it was "plausible" that more than one-half of the non-Medicare or non-Medicaid patients would be receiving free services. Given that Medicare and Medicaid would be charged at the "regular rate," the provision of free testing services "would essentially result in a two-tiered pricing structure." The OIG stated that "[w]ithout examining the data from every physician practice . . . we cannot determine whether the [laboratory providing the free tests] would violate the substantially in excess provision." However, according to the OIG, it had "sufficient information" to conclude that the proposed arrangement posed too high of a risk of violating this prohibition to "grant it prospective immunity" under OIG authorities.

Ober | Kaler Comments

The OIG concluded that under certain facts, providing free testing to individuals subject to Exclusive Plans may be unlawful. The facts on which the OIG based its conclusion, however, will be present only infrequently, i.e., when physicians are required to pay a monthly maintenance fee for a laboratory interface. Therefore, free testing may continue to be a reasonable compliance strategy under most circumstances. Laboratories, however, should use due care in determining when it may be offered.