Oncologists and the Stark Law

By Terry S. Coleman, Esq.

The so-called Stark law, named after its sponsor, Congressman Pete Stark, was enacted in 1989 to address what was seen as excessive ordering of ancillary services by physicians who owned the equipment with which the services were furnished.¹ Over the years, the Centers for Medicare & Medicaid Services (CMS) has issued a series of regulations establishing a complex set of interpretations of the law.²

The Stark law generally prohibits physicians from referring Medicare and Medicaid patients for specified “designated health services” to entities with which they, or their immediate families, have a financial relationship. This prohibition is broader than it might seem, since a physician’s own group practice is viewed as an entity receiving referrals when a physician asks a staff member to provide a service to a patient. The Stark law also contains many exceptions, however, and when the terms of those exceptions are satisfied, the law allows much activity that would otherwise be prohibited.

For oncologists, a primary issue under the Stark law is whether they can furnish the designated health services, such as laboratory and radiologic services, to their patients in their own offices. The exception for in-office ancillary services allows these services to be furnished with some limitations—for example, office staff cannot furnish durable medical equipment to patients, with the exception of ambulatory infusion pumps and a few other items.

The Stark law restricts the manner in which revenues from designated health services can be divided among physicians in a group practice. In general, the income of a particular physician cannot be based on the billings generated by that physician for designated health services. Thus, practice revenue from laboratory and radiologic services must be divided by some other method, such as equal shares among all the physicians in the group. Drug

administration services are not designated health services, so physicians can be paid based on productivity with respect to those services.

An important area of some ambiguity is revenue from drugs. Commentary issued by CMS in connection with the regulations clearly states that the income of individual physicians in a group practice may be based on the revenue each physician generates from incident to services, such as drugs administered in the office.³ The text of the regulation

itself, however, is less clear.⁴ ASCO submitted comments after the regulations were issued, requesting that the text be clarified, but CMS has not yet responded.

Financial relations with outside entities to which a physician refers patients often present issues that are difficult to analyze under the Stark law. A physician may lawfully refer to an entity with which the physician has an arrangement to provide services, such as consulting or medical direction, if the payment amount is fair market value for the services furnished. The payment amount cannot vary depending on the level of referrals.

Referrals to large, publicly held companies in which the physician has an investment interest are permitted, but referrals to small companies or joint ventures in which the physician has an investment interest are permitted only under certain circumstances. The regulations are so complex on this topic that each arrangement must be carefully analyzed to determine whether it is permitted.

References

1. Social Security Act, § 1877; 42 United States Code § 1395nn.
2. 42 Code of Federal Regulations §§ 411.350-411.356.
3. E.g., 66 Federal Register 856, 876, 908-09 (Jan 4, 2001); 69 Federal Register 16054, 16080 (Mar 26, 2004).
4. 42 Code of Federal Regulations § 411.352(i).

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