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ResearchReport

Federal Stark Law Applicability

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Issue

Does the federal physician self-referral law (also known as the "Stark law") apply only to Medicare and not Medicaid?

Stark Law

The federal Stark law generally prohibits physicians from referring patients to receive "designated health services" payable by Medicare from entities with which the physician, or the physician's immediate family member, has a financial relationship (i.e., ownership or investment interests or compensation arrangements). It also prohibits an entity from presenting or causing to be presented a bill or claim to anyone (i.e., individual, entity, or third-party payor) for designated health services provided as a result of a prohibited referral.

Under the law, "designated health services" include:

1. clinical laboratory services;
2. physical therapy, occupational therapy, and outpatient speech-language pathology services;
3. radiology and certain other imaging services;
4. radiation therapy services and supplies;
5. durable medical equipment and supplies;
6. parenteral and enteral nutrients, equipment, and supplies;
7. prosthetics, orthotics, and prosthetic devices and supplies;
8. home health services;

9. outpatient prescription drugs; and
10. inpatient hospital services (42 U.S.C. § 1395nn (§ 1877) and 42 CFR §§ 411.350–411.389).

Applicability to Medicare and Medicaid

According to the federal Centers for Medicare and Medicaid Services (CMS), the Stark law applies to both Medicare and Medicaid claims. When the Stark law was first enacted in 1989, it applied only to physician referrals for Medicare clinical laboratory services. But in 1993, Congress passed legislation (known as "Stark II") that expanded the self-referral prohibition to include the above designated health services and extended the self-referral prohibition to Medicaid. It did so by adding a provision in Title 19 of the Social Security Act that prohibits states from receiving federal Medicaid payments for designated health services provided based on a physician referral that, if made for a Medicare patient, would violate the Stark law (42 U.S.C. 1396b (§ 1903(s)).

Additionally, recent federal district court opinions have held that the Stark law applies to Medicaid claims. For example, in *U.S. ex rel Baklid-Kunz v. Halifax Medical Center* (2012), the Department of Justice alleged that Halifax Medical Center violated the Civil False Claims Act (31 U.S.C. §§ 3729-3733) by causing the Florida Medicaid program to submit claims to the federal government based on physician referrals prohibited under the Stark law. The court held that Section 1903(s) extends the Stark law's applicability to Medicaid claims and that the allegations that Halifax Medical Center caused the Florida Medicaid program to submit false claims for federal Medicaid payments were sufficient to deny Halifax Medical Center's motion to dismiss the case (the case was later settled).

Exceptions

The Stark law contains several exemptions that address different types of patient referrals, such as referrals to (1) other physicians working in the same group practice; (2) ancillary services in the same group practice (e.g., laboratory, radiology, or outpatient pharmacy services); and (3) for-profit hospitals the physician is invested in, if the investment is in the hospital as a whole and not a specific department.

Violations

The Stark law is a strict liability statute and does not require proof of a physician's specific intent to violate the law. Violators are subject to fines and exclusion from participation in Medicare and Medicaid. In 2016, CMS published an interim final rule that increased the maximum civil penalty for Stark law violations from $15,000 to $23,863 per violation.
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