



AN ASSOCIATION OF
MONTANA HEALTH
CARE PROVIDERS

May 27, 2008

To: Pat Murdo, Legislative Services Division
Fr: Robert W. Olsen, Vice President
Re: Background Information Pertaining to Federal Stark and Anti-kickback Laws

A good number of our concerns and objections to the current draft language of LC 0038 hinge on the issues of current federal anti-kickback and Stark self referral laws. We offer this analysis performed by Drinker, Biddle and Reath, LLP for your information.

I. Background

While patients have the ultimate decision-making power for their health care, they often rely on their physicians' professional judgment with regard to the specifics of the health care services they receive. Therefore, physicians can be influential in directing their patients toward health care services. Individuals and other entities, such as other health care providers and insurance networks, among others, also can influence patient referrals for health care services.

A. The Anti-Kickback Statute – In general

In the early 1970's, Congress became concerned that health care decision-making could be unduly influenced by individuals' motives for profit.¹ Thus, in 1972, Congress enacted the federal Medicare and Medicaid Anti-Kickback Statute (the "Anti-Kickback Statute") to prohibit unethical practices leading to increased costs for the Medicare and Medicaid programs.² The purpose of the Anti-Kickback Statute was and remains to guarantee objective medical advice for federal health care program beneficiaries and to ensure that providers refer patients based on the patients' best medical interests and not because the providers stand to profit from the referral.³

To that end, the Anti-Kickback Statute makes it a felony for any individual to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce the

¹ 63 Fed. Reg. 1662 (January 9, 1998).

² H.R. Rep. No. 231, 92d Cong., 1st Sess. 108-08, reprinted in 1972 U.S.C.C.A.N. 5093.

³ News Release, Office of Inspector General, November 18, 1999.

referral of business covered by a federal health care program.⁴ The statute imposes civil monetary penalties when there is “reckless disregard” or “deliberate ignorance.”⁵

B. The Stark Law – In general

In the 1980’s, the federal government perceived that physicians with financial interests in health care entities over-utilized certain services. This prompted Congress to sponsor a study in June 1988 to determine whether physicians referred more often to facilities that they owned or in which they invested.⁶ The Office of Inspector General (“OIG”) conducted the study and found that patients of physicians who owned or invested in independent clinical laboratories received 45 percent more laboratory services than Medicare patients overall.⁷

After the 1988 OIG study, other studies also found that physicians’ financial interests in health care entities, including diagnostic imaging centers and physical therapy and rehabilitation centers, resulted in increased utilization and higher prices.⁸ These studies

⁴ 42 U.S.C. § 1320a-7b; Social Security Act § 1128B.

⁵ Specifically, the Anti-Kickback Statute imposes criminal and civil penalties against any individual or entity that:

[K]nowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in Part under [Medicare or a state health care program], or

(B) to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in Part under [Medicare or a state health care program].⁵

The Anti-Kickback Statute also contains a reciprocal provision making it illegal to solicit or receive remuneration in return for a prohibited referral or for purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering any good, facility, service or item for which payment may be made in whole or in Part under Medicare or a state health program.⁵

Violation of the Anti-Kickback Statute is a felony and can result in imprisonment of up to five years and/or a fine of up to \$25,000 for each offense. In addition, a conviction results in the automatic exclusion of the offender from the Medicare and state health programs for at least five years.⁵ A person who is deemed to have committed an act described in the Anti-Kickback Statute may be excluded from the Medicare and state health programs in a civil exclusion proceeding, even if no criminal prosecution is initiated.⁵ To prove a criminal case, which results in mandatory exclusion, the government must prove its case beyond a reasonable doubt. In contrast, the government need only prove its case by “a preponderance of the evidence” to prevail in a civil exclusion proceeding.

The Anti-Kickback Statute contains exceptions for certain payments, including for *bona fide* employment relationships.⁵ Payments that meet these exceptions will not be considered illegal remuneration under the Anti-Kickback Statute.

⁶ 63 Fed. Reg. 1661

⁷ “Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress,” Office of Inspector General, DHHS, page 18 and 21 (May 1989).

⁸ 63 Fed. Reg. 1661.

show that when physicians have financial interests in health care entities or are given incentives to refer patients to an entity, the physicians may over-utilize services by ordering services that they would not have absent a profit motive, resulting in an adverse impact on patients' health and increased costs to the government.

Thus, in November 1989, Congress enacted Section 1877 of the Social Security Act (also known as the "Ethics in Patient Referrals Act of 1989" and, more commonly, as the "Stark Law") to address these issues. Under the Stark Law, if a physician or the physician's immediate family member has a financial relationship with a health care entity, the physician may not make referrals to that entity for "designated health services" covered by the Medicare program unless an exception applies.⁹ Designated health services ("DHS") include:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

Violation of the Stark Law results in failure to receive payments from Medicare for services so rendered, as well as possible civil fines to both the referring physician and the entity.

In 1993, Congress amended Section 1903(s) of the Social Security Act to extend aspects of the referral prohibition to the Medicaid program. Under Section 1903(s), state Medicaid programs are denied payment for certain expenditures for DHS based on a physician referral if payment for the DHS would be denied under Medicare. While the Stark Law technically has been extended to apply to referrals for DHS covered by Medicaid, the applicability of the Stark Law to Medicaid-covered services will not take effect until final regulations applicable to the Medicaid program are promulgated. Such regulations have not yet been enacted.

Since the Stark Law was enacted, the Centers for Medicare and Medicaid Services ("CMS") (formerly the Health Care Financing Administration) have issued multiple sets of regulations implementing the law as applied to Medicare patients. With each phase of regulations, public comments and responses from CMS are published. The result is thousands of pages of guidance on the Stark Law, including questions from commenters and answers from CMS regarding the intended scope and application of the law in specific circumstances. Collectively, this guidance informs health lawyers' analysis of how the law is

⁹ 42 U.S.C. § 1395nn.

intended to apply to additional situations not specifically discussed. Thus, while the Stark Law's general referral prohibition and specific exceptions provide basic rules to follow, the additional guidance of the many iterations of proposed and final rules and the commentary associated therewith provides significant additional information regarding how to apply the law in practice.

C. Applicability of Stark/Anti-Kickback Statute to Employed Physicians

Despite the broad applicability of the Anti-Kickback Statute and the Stark Law, each contains far-reaching exceptions as applied to employed physicians. More specifically, the Anti-Kickback Statute does not apply to employment relationships. According to the regulations issued pursuant to the Anti-Kickback Statute, the word "remuneration" does not include any amount paid by an employer to an employee who has a bona fide employment relationship with the employer.¹⁰ Similarly, from the time the Stark regulations were first proposed, an exception for financial relationships between physicians and employing entities, such as hospitals, was provided.¹¹ The exception for bona fide employment relationships covers compensation arrangements between employers, including hospitals, and physicians if the following conditions are met:

- The employment is for identifiable services.
- The amount of the remuneration under the employment is—
 - Consistent with the fair market value of the services; and
 - Not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals for DHS by the referring physician.
- The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.
- The employment meets such other requirements as the Secretary of Health & Human Services may impose by regulation as needed to protect against program or patient abuse.¹²

In the commentary to the Phase I regulations issued under the Stark Law, CMS explained its concern that, while it hoped to include in the bona fide employment exception requirements that would not impose a significant burden on employing entities,¹³ it similarly was concerned that even fixed payments from an entity to a physician could be found to take the volume or value of referrals into account if the payments to the physician exceeded fair market value.¹⁴ Therefore, CMS added the above conditions to the bona fide employment

¹⁰ 42 C.F.R. § 1001.952(i).

¹¹ 63 Fed. Reg. 1700.

¹² 42 U.S.C. § 1395nn (d)(2).

¹³ 66 Fed. Reg. 878 (January 4, 2001).

¹⁴ *Id.*

exception. CMS believed the conditions would not be overly burdensome because they were likely already to be required under existing laws and most contracts.¹⁵

Under the Stark Law's employment exception, employers are expressly permitted to pay their physician-employees productivity bonuses based on services the physician personally performs.¹⁶ CMS noted that the Stark Law contemplates that physician-employees may be paid in a manner that directly correlates to their own personal labor.¹⁷ By contrast, payments for an employee's productivity in generating referrals of DHS performed by others are not permitted.¹⁸

In the commentary to the Phase II Final Regulations issued under the Stark Law, CMS also discussed exclusive contracting arrangements, including non-compete provisions, between hospitals and physicians.¹⁹ CMS noted that such arrangements can serve legitimate business purposes and do not raise substantial concerns under the statute or regulations – provided that these payments are for personally performed services and do not take into account the volume or value of referrals generated between the parties.²⁰

D. Applicability of Stark Law/Anti-Kickback Statute to Employer-Directed Referrals

Under the Stark Law, a physician's compensation from a *bona fide* employment or other contract for personal services may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier. The Stark Law requires only that the compensation arrangement:

- (1) is set forth in writing;
- (2) is set in advance for the term of the agreement and does not vary based on volume or value of referrals to the related party;
- (3) is consistent with fair market value; and
- (4) otherwise meets a Stark Law exception.²¹

Further, required referrals are permissible only if they relate solely to the physician's services covered by the scope of the employment or other contract.²² In addition, the referral requirement must not apply if the patient expresses a preference for a different provider, the

¹⁵ *Id.*

¹⁶ *Id.* at 16086.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.* at 16088.

²⁰ *Id.*

²¹ 42 C.F.R. § 411.354(d)(4).

²² 69 Fed. Reg. 16069 (March 26, 2004).

patient's insurer determines the provider, or the referring physician determines that the referral is not in the patient's best interest.²³

In the commentary to the Phase II Final Rule, commenters objected to employers being allowed to require their employees to make referrals to certain DHS entities.²⁴ Also, entities outside of integrated health systems objected to allowing required referrals, believing themselves to be competitively disadvantaged by the rule.²⁵ In response to these comments, CMS noted that in certain circumstances, required referrals are a reasonable and appropriate aspect of health care business arrangements, and should not implicate the Stark Law, provided that the required referrals relate solely to the physician's services covered by the scope of the employment or other contract. CMS further explained that it is permissible for employers to require their employees, when working in their capacity as employees, to refer to employer-affiliated entities.²⁶

Another Phase II commenter expressed concern that physicians employed by health care systems were pressured into referring to DHS entities within the same health system, sometimes without regard to a patient's best interest.²⁷ In response, CMS noted that while referral requirements should not interfere with a physician's medical judgment, the Stark Law was not intended to interfere with legitimate employment and health system structures.²⁸ Therefore, CMS continues to allow employer-directed referrals as long as the conditions for the bona fide employment exception are met. According to CMS, its rule strikes a balance between the legitimate business needs of employers and health systems and the protection of patient choice and judgment.²⁹

In the commentary to the Phase III Final Rule, a commenter raised the issue that allowing an employer to condition employment on an agreement to refer patients to a particular provider may implicate the Federal Anti-Kickback Statute, as well as antitrust and other unfair trade practices laws.³⁰ In response, CMS noted that arrangements that include referral requirements could potentially implicate the Anti-Kickback Statute, and should be scrutinized to ensure that no purpose of the compensation is to induce or reward referrals.³¹ However, the potential for implication of the Anti-Kickback Statute was not enough to warrant CMS withdrawing the employer-directed referral exception.³²

²³ *Id.*

²⁴ 69 Fed. Reg. 16069.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.* at 16087.

²⁸ *Id.*

²⁹ *Id.*

³⁰ 72 Fed. Reg. 51031 (September 5, 2007).

³¹ *Id.*

³² *Id.*