

Anti-Kickback and Self-Referral Laws

By: Daniel Sroka, Esq.

For several years and at an accelerating pace, Bentson Clark & Copple's phone has been ringing with orthodontists on the other end asking our advice on "how to partner with a general or pediatric dentist." The conversation starts with various scenarios:

1. One of my top referrals has invited me to see patients in his/her office. I'm afraid if I don't do this he/she will hire another orthodontist and my referral relationship will end.
2. Pediatric and general dentists in my town that once referred to me have hired an orthodontist as an employee to treat patients in their office. I have a pediatric or general dentist that still refers to me, how can we partner together?
3. I want to open a satellite with a referring pediatric dentist or dentist, how should this be structured?
4. I'm just getting out of my program and a good friend (or my spouse) is a pediatric dentist or general dentist, we want to partner together as we start out. How should we do this?

There are other variations on the theme of course, and the answers of "how to structure a relationship with a pediatric or general dentist" necessarily need to fall within what federal and state laws and ethics requirements for specialists dictate.

This article is a primer written by Bentson Clark & Copple's preferred attorney, Daniel Sroka, Esq., outlining current legal considerations around which you have the freedom to structure a business relationship with other dentists or dental specialists. It is worth emphasizing that this article is not meant as legal representation or legal advice. Counsel on your behalf needs to be retained to assure any business relationship you are contemplating falls within the guidelines set forth both federally and at the state level and is compliant with ethics rules you are bound to uphold. Please note that the following is for informational purposes only and does not constitute legal advice. No attorney-client relationship is hereby created between Daniel Sroka, PC and any person or entity. Please consult with your legal counsel with respect to any of the following matters that affect you or your practice. Enjoy the following article from Daniel Sroka.

- Chris Bentson

There are four legal prohibitions against a physician receiving a financial benefit in exchange for referring a patient to a particular medical care provider:

- The "Stark" law, which applies to Medicare self-referrals.¹
- The federal Anti-Kickback law, which applies to all patient referrals where federal or state approved or funded health care is involved.
- State equivalents of the Stark law and the federal Anti-Kickback law.
- Ethics rules applicable to physicians.

In at least two respects, these laws are a point of emphasis for orthodontists. First, the trend of orthodontists and pediatric dentists to establish business relationships

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Telephone: (336) 379-8822 / (800) 621-4664
Fax: (336) 333-0015
Website: www.bentsonclark.com
Email: info@bentsonclark.com

Editorial Address:
397 South Swing Road
Greensboro, NC 27409

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is driven in large part, if not primarily, by the patient referrals that will be generated by the pediatric dentist for the orthodontist. Second, the historical referral relationship between general dentists in vicinity of an orthodontic practice is a valuable asset in the context of a sale of an orthodontic practice.

1. Stark

In general, the Stark law (a/k/a the "self-referral law")² prohibits (a) a physician from referring a Medicare patient to a medical practice in which the physician or any member of the physician's family has an ownership interest or financial relationship, and (b) a medical practice that has accepted a patient from a prohibited referral from filing a claim for Medicare reimbursement with respect to such patient.

Unlike many statutes, where some level of intent to violate the law must be shown in order to prove a person's culpability, the Stark law is violated whether or not there was an intent to do so, i.e., it applies a "strict liability" standard. For example, if a physician who owns a practice that accepts Medicare refers a patient to his own practice not knowing that the patient was a Medicare patient, the physician has violated the Stark law.

The Stark law recognizes certain exceptions, including the following:

- A physician may refer a Medicare patient to a "group practice" in which the referring physician is one of the owners, provided that the Medicare services are performed by, or under the supervision of, a physician in the group other than the referring physician. The definition of "group practice" is detailed; the essence of the exception is that so long as the Medicare income generated by the referral is earned by a physician in the practice other than the physician who referred the Medicare patient to the practice, then the referral is not prohibited by the Stark law. The exception further prohibits the physicians within the group practice from using compensation formulas to later re-allocate Medicare income to the referring physician.
- A group practice may provide certain medical services and products that are reimbursable under Medicare to a patient who was self-referred if such services and products are truly ancillary to other non-Medicare services and products provided by the group practice to that patient. Some examples include outpatient prescription drugs and durable medical equipment.

Other, even more fact-intensive, exceptions are recognized under the Stark law. However, each is bounded by significant organizational, technical, and/or financial hurdles,

which must be carefully scrutinized in order to assure that the exception is met.

All penalties imposed for violations of the Stark law are civil, as opposed to criminal, in nature. The penalties can be significant, and include up to \$15,000 per violation, liability under the federal False Claims Act of up to \$10,000 per violation, treble damages, and the expenses of litigation.

2. Federal Anti-Kickback Law

The federal Anti-Kickback law³ prohibits a person from receiving anything of value in exchange for referring a person to a physician for treatment where any portion of the referred patient's treatment fee is payable pursuant to a "Federal health care program." Since the statute defines "Federal health care program" as a program approved by federal or state law and/or funded with federal funds it would apply to many, if not most, patients with health insurance or health care benefits.

The federal Anti-Kickback law is broader than the Stark law in that it:

- Applies to anyone making a referral, whether or not a physician.
- Applies whether or not the person making the referral has an ownership or financial interest in the practice receiving the referral.
- Sanctions both the party making the referral and the party receiving the referral.
- Imposes both civil and criminal penalties, including imprisonment.

An element of the federal Anti-Kickback law that is narrower than the Stark law pertains to the state of mind of the person accused of violating the law. Under Stark, state of mind is irrelevant; Stark is violated whether or not the accused party intended to violate it. Under the federal Anti-Kickback law, the accused person's wrongful intent must be proven. Initially, the burden used in federal Anti-Kickback litigation was to prove that the accused person both knew of the existence of the federal Anti-Kickback law and willfully violated it. The Affordable Care Act removed the element that the accused person must have intended to violate the Anti-Kickback law, meaning that the burden now is simply to prove that the accused person intended to receive a kickback that the person knew was in some manner illegal.

The most significant practical difference between the Stark law and the federal Anti-Kickback law is that under the latter the party making the referral must have received something of value as an inducement to make the referral. Such remuneration could be many things, ranging from money, to

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gifts, to sales at prices less than market value, to forgiveness of debts. Examples from litigated cases include frequent flier miles, free attendance at training seminars, and free medical supplies provided to the referring party in exchange for a certain volume of referrals.

The federal Anti-Kickback law includes several safe harbors⁴ which, if satisfied, place the particular referral relationship outside the scope of the law's prohibitions. In general, the safe harbors apply where a referral is made incident to a separate business relationship between the party making the referral and the party receiving the referral and generally require that such business relationship be premised upon transactions made for fair market value and at arm's-length. There are currently twenty-three safe harbors, including the following:

- A lease relationship between the parties
- An investment relationship between the parties
- Group purchasing contracts
- Sharing of employees

3. State Anti-Kickback Laws

At least thirty-six states have laws that mimic or supplement the Stark law, the federal Anti-Kickback law, the federal False Claims Act, or a combination thereof. Although the constitutional principle of federal preemption⁵ sometimes arises in the context of such state laws, in general they have been found to be enforceable alongside the federal laws.

4. Ethics Rules

The American Medical Association, the American Dental Association, and state medical boards prohibit fee-splitting⁶ and engagement in undisclosed conflict of interest transactions.⁷ Consequently, in addition to the adverse effects of being found liable under a state or federal law for engaging in a prohibited referral, a physician's professional standing and licensure can be impacted by the same conduct.

5. The Ortho-Pedo Relationship

The trend in which orthodontists and pediatric dentists are intensifying their business relationships can implicate some or all of the above-referenced laws and rules. The engine driving orthodontists to establish such relationships is to increase referrals. The danger lies in how to motivate the pediatric dentist to move forward with the relationship with a particular orthodontist without violating federal and state laws and rules pertaining to referrals.

Clearly, paying the pediatric dentist for orthodontic referrals could violate, at a bare minimum, the federal Anti-Kickback law. Variations on the theme - such as sharing office space with a pediatric practice at no cost, providing shared medical equipment and/or personnel to the pediatric dentist at

no cost, or other means by which the normal expenses of the pediatric dentist's practice are subsidized by the orthodontist - could also constitute prohibited remuneration under the federal Anti-Kickback law.

So what's an orthodontist to do? Fortunately, the safe harbor provisions of the federal Anti-Kickback law explain how an orthodontist and a pediatric dentist may create a business relationship that will pass anti-kickback muster.

The physical proximity of the orthodontic practice and the pediatric practice will be fundamental to their relationship. With both practices under one roof, a dental patient in need of braces need only walk across the hall to meet a willing orthodontist, who, at least by inference, the patient will understand as having been approved by the pediatric dentist. Additionally, the patient's ability to schedule dental and orthodontic appointments for the same day and at the same location, the patient's confidence in knowing that both dental providers appear to be running coordinated practices (whether or not they actually are), and the benefit of having to become acquainted with only one set of staff members as opposed to two are among the synergies created by the ortho-pedo relationship.⁸

The pediatric dentist, logically, may be looking for something in return, which is where the safe harbors come into play. The safe harbors will allow the two practices to co-own or co-lease a common facility, to share the costs of services and equipment, and to share the costs of employees, all without actually having to become partners or shareholders of the same practice. However, there are many technical requirements that must be met in order for the safe harbors to apply. For example:

- In order for an office lease⁹ between referring physicians to fall within the applicable safe harbor:
 - ▶ The lease must be in writing and signed by both parties
 - ▶ If the lease provides for the use of portions of the premises by the pediatric practice on some dates and by the orthodontic practice on others then the lease must specify exactly what those dates and times are throughout the entire term of the lease
 - ▶ The term of the lease must be for at least one year
 - ▶ All monetary provisions of the lease, whether rent or pass-through expenses, must be specified and quantified
 - ▶ Rent must not only be at market value but also must be determined as if the premises were being leased for general commercial purposes, as opposed to being leased with the expectation of a captive referral base being created

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- In order for shared employee expenses to qualify for the applicable safe harbor:
 - ▶ The agreement pursuant to which employees and their related expenses are shared must be in writing and have a term of at least one year.
 - ▶ Employee compensation and related costs must not exceed the actual value of the services provided by the employee.
 - ▶ Employee compensation for the term of the agreement must be expressly stated in the agreement.

6. Referring General Dentists

Even outside the context of an ortho-pedo business arrangement, the laws governing patient referrals and kickbacks must remain a focus for orthodontists. For example, the ongoing relationships between an orthodontic practice and general dentists in the same locale must not be based on remuneration from the orthodontist to the referring dentist. Of course, customary business entertainment of referring dentists by orthodontists is permissible; however, if such entertainment and/or other benefits become either too significant or are ratcheted upward or downward based upon promised and/or historical referral volume then a prohibited kickback relationship might be present.

7. Recent Events

Litigation and enforcement of the federal statutes pertaining to prohibited kickbacks and self-referrals have typically involved entities such as pharmaceutical companies and hospitals. Notably, one case ended in a \$125 million settlement paid by a subsidiary of drug manufacturer Warner Chilcott for paying kickbacks to physicians who prescribed certain osteoporosis medications. Although the U.S. Department of Justice's (DOJ) recent focus has been on larger enterprises, the scope of the DOJ's jurisdiction certainly includes relatively smaller markets, such as dentistry. Also, there appears to be an uptick in the federal government's focus on anti-kickback laws, evidenced in part by new guidelines being issued to the Office of Inspector General earlier this year as to how to address this type of claim.

8. Summary

A good rule of thumb for this area of the law is that if it looks like an impermissible referral, walks like an impermissible referral, and quacks like an impermissible referral, it is probably an impermissible referral. Efforts to circumvent the anti-kickback laws by creating indirect or delayed compensation, in-kind compensation, or other creative structures between physicians are unlikely to succeed. Although pediatric dentists may seek something more from an orthodontist than some costs savings resulting from sharing

facilities, personnel, and purchases of supplies/equipment, the orthodontist must ensure that any financial benefits flowing to the referring pediatric dentist are within a safe harbor.¹⁰ 

Endnotes

¹ The question of whether or not Stark also applies to Medicaid is still being addressed by the courts.

² 42 U.S.C. sec. 1395 nn

³ 42 U.S.C. sec. 1320a-7b(b)

⁴ 42 C.F.R. 1001.952 et seq.

⁵ Under Article VI, Clause 2 of the United States Constitution, when a federal law and a state law conflict, the federal law shall prevail. In instances where the state law is stricter than the federal law, the state law often will be permitted to apply.

⁶ American Dental Association Advisory Opinion 4.E.1.

⁷ American Dental Association Advisory Opinion 5.C.

⁸ In addition to compliance with anti-kickback laws, sharing facilities and/or staff can raise several other legal issues, including the following: (i) HIPAA compliance: In addition to each practice maintaining HIPAA compliance for its internal operations, each practice must also implement HIPAA-compliant procedures based on their staff members having access to patient information of the other practice; (ii) Income taxes: If there are to be shared staff members, typically they will be employed by one practice and 'leased' part-time to the other, as opposed to the staff member having dual employment. Under such an arrangement, payroll taxes and other withholding taxes must be calculated correctly to ensure that each practice's share of such taxes is accurate and is reported correctly to the taxing authorities; (iii) Insurance: If any of the shared staff members are medical, as opposed to administrative, then their respective malpractice policies must be structured so as to provide coverage both for the practice that actually employs the staff member and the practice that leases that staff member from the employing practice; and (iv) Deemed partnerships: As a general proposition, state laws provide that if two persons hold themselves out to the public as being partners in the same business, the public may be entitled to presume that there is indeed a legal partnership, even though, in fact, the two persons are not partners. Since, under those same applicable laws, one partner can be held liable for the wrongful acts of the other partner, it is important for two physicians to avoid being viewed as partners if they in fact are not. Accordingly, the orthodontic practice and the pediatric practice must take precautions in such areas as building signage, advertising, and web sites, not to co-brand their services or otherwise imply that they are operating a single dental practice.

⁹ The safe harbor for equipment leases follows generally the same approach.

¹⁰ The safe harbor provisions of the federal Anti-Kickback law are not the sole means by which physicians can create a legal referral relationship, i.e., it may well be that a relationship not listed in the safe harbors may be found by a court to be legal. However, the practical approach will be to operate solely within the safe harbors, as opposed to being selected by the government or a patient as a test case for litigation.

Daniel Sroka is the owner of Daniel Sroka, PC, a law firm located in Greensboro, North Carolina. He is a graduate of the University of Wisconsin (B.B.A. 1985) and of Wake Forest University Law School (J.D. 1989). In addition to medical practice transitions, his scope of practice includes mergers and acquisitions, corporate transactions, commercial real estate, business formation and structuring, and intellectual property licensing. He, his wife Kelly, and their three children reside on a horse farm in rural Stokes County, North Carolina.

