

Health Compliance Issues for Dentists and Orthodontists

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According to Colgate.com, dentists are professionals who complete four years of undergraduate school and four years of dental school. Dentists must then pass a written test and a clinical licensing exam before they can become qualified to practice. Dentists generally use one of the following designations.

- DDS (Doctor of Dental Surgery)
- DMD (Doctor of Medicine in Dentistry or Doctor of Dental Medicine)

Orthodontics is a dental practice specialty that requires additional training. About six percent of all dentists are orthodontists. Orthodontists normally have to complete a two/three-year residency program.

According to the American Association of Orthodontists (AAO), dentists:

- Provide regular checkups
- Diagnose and treat cavities
- Treat mild gum disease and oral hygiene problems.
- Extract teeth that cannot be saved
- Work on teeth by *“applying bonding, veneers or crowns to teeth that are broken, chipped, misshapen or severely decayed.”*
- Look for signs of oral diseases
- Give advice on oral health

According to the AAO, orthodontists *“specialize in aligning the jaws, and moving the teeth.”* These professionals *“correct crowded teeth, gaps between teeth, teeth that stick out, and jaws that don’t align properly.”*

Dentists use various medical products including *“braces, lingual braces, and clear aligners.”* Dentists usually work with X-rays and photographs.

Dental practices usually include the dentist, dental assistants, dental hygienists, and dental technicians. While most dentists work in private practice, dentists also work in dental hospitals, the military, and prisons.

Dentistry/orthodontist practice and illegal referrals. Kickbacks, and improper fee-splitting

Professionals who work in dentistry, orthodontics, and other medical-related fields often work with other professionals. For starters, dentists often refer patients to orthodontists. Orthodontists work with various medical device companies. Dental professionals may work with diagnostic labs, medical suppliers, cosmetic companies, and other businesses.

Dental professionals need to understand what financial relationships are permissible and what relationships may lead to charges the professional relationships violate Stark Law, the Anti-Kickback Statute (AKS), or other related laws.

Many of the cases that the US Department of Justice settles in civil fraud cases involve the healthcare profession. These cases include hospitals, drug manufacturers, and many different types of healthcare practices. The best course for any type of dental practice is to consult with an experienced California health lawyer before starting the practice or starting any new professional relationships.

Your lawyer will review which compliance laws apply to the dental profession. He'll explain that referrals of patients to any entity the dental practice has a financial relationship or stake in – are especially suspect. The lawyer will also explain what exceptions and “safe harbors” to these laws can help protect your professional relationships – when the fees for services or products are paid by federal or state government programs. Many dental patients, for example, use Medicare or Medicaid to pay for their dental care.

Your lawyer will review, among other compliance issues:

- What types of referral arrangements are permissible
- What marketing strategies can be used to entice patients to use your dental or orthodontist practice
- How a properly managed service organization (MSO) can be used to protect your practice.

What do dental practices need to know about Stark Law?

Stark Law prohibits doctors from referring patients who use Medicare from referring that patient to a “designated health service” with which the dentist has a “financial relationship.” The idea behind the law is that dentists should refer patients based on what is best for the patient’s health – and not what is best for the dentist’s finances.

Stark law does provide numerous exceptions which we have discussed in many articles. There are specific requirements for each type of exception. Some of these exceptions include:

- In-office ancillary services
- Office space rental
- Preventive services
- Equipment rental
- Physician recruitment
- Many other relationships

Dentists and dental practices who violate Stark Law can be held civilly liable. Civil liability means paying back to Medicare any improper payments. Civil liability also the possibility of statutory fines and exclusion from Medicare.

Dentists need to understand that Stark Law is fairly strict. There’s no formal requirement that the government needs to show the dentist intended a violation of the law – in order for the dentists to be found liable. The establishment of the referral through Medicare and the designated health service is enough to hold the dentist liable.

Stark law does apply to dentists – though there is a practical concern. Medicare generally does not cover dental payments

which means most dentists do not submit bills to Medicare.

What Medical Practices Should Know about the Stark Law

The Stark Law is named after California U.S. Congressman, Peter Stark. It seeks to regulate how physicians refer Medicare and Medicaid patients. The law is part of the Omnibus Budget [...]

Exceptions to the Stark Law Prohibition of Medical Referrals

The Stark Law governs what types of referrals doctors can make if they bill for Medicare and Medicaid. The presumption is that that referrals made by a doctor to a designated health service are [...]

What do dental practices need to know about the Anti-Kickback Statute

The Anti-Kickback Statute also regulates the referral relationship. Generally, the AKS prohibits referrals that are based on providing anything of value to induce the referral – such as cash, free vacations, speaking engagements, and other items dentists might consider valuable.

There are many similarities but also critical differences between the AKS and Stark Law.

- The AKS uses the term “safe harbors” instead of exceptions.
- The AKS applies to referrals of patients covered by Medicaid and other federal programs – in addition to Medicare. While Medicare generally does not cover dental services, most state Medicaid programs do cover dental services.
- The AKS is a criminal statute unlike Stark Law which is civil in nature. The AKS requires that the government show criminal intent. If convicted, a dentist or any physician can be sentenced to prison and ordered to pay substantial fines and penalties.

Dentists who violate Stark Law or the AKS may also be in violation of comparable state laws. Dentists may also lose their license to practice dentistry or their dental specialty.

Some of the AKS safe harbors include:

- The use of a Managed Service Organization (MSO)
- Renting space arrangements
- The sale of a medical practice
- Equipment rentals
- Personal service contracts
- Group purchase organizations
- Incentives for rural practitioners

Use an MSO to Comply with Federal Anti-Kickback Safe Harbors

What can an MSO, a Management Services Organization, do to augment your healthcare compliance?

How are referrals between dentists and orthodontists reviewed?

As a practical matter, many dentists refer their patients who need specialized dental care to orthodontists. Dentists and

orthodontists should review their relationships with an experienced healthcare lawyer. The relationship may cause legal compliance issues if there is a financial relationship between the dentist and the orthodontist. It is generally permissible to refer patients to each other if the referral is based on merit and neither the dentist nor the orthodontist has a financial stake in the other's business (which may indicate a Stark Law compliance violation)– and there is no quid pro quo or exchange based on the referral (which could indicate a violation of the Anti-Kickback Statute).

Some of the issues that may indicate a Stark Law or AKS problem include:

- If one practitioner has an employment relationship with the other practitioner
- If one practitioner leases dental office space from the other practitioner

These two examples and many other relationships may be more likely to be considered in compliance with these laws if the relationships are structured, with the help of a skilled healthcare compliance lawyer, to meet a Stark Law exception or an AKS safe harbor.

HIPAA and dental care compliance issues

Dental practitioners, orthodontists, and all other types of related practices need to consider HIPAA compliance requirements.

All dental professionals need to ensure that they comply with HIPAA (Health Insurance Portability and Accountability Act of 1966). This includes understanding what records can and cannot be exchanged (and how the records can be exchanged) – if a dental practitioner refers a client to an orthodontist, diagnostic center, or other dental practice – or even if there is no referral.

It is also a violation of HIPAA for a dental practitioner or dental specialist to offer an incentive (such as a discount) to a patient who uses Medicare or Medicaid – with the aim of influencing that patient to recommend the dental practitioner/dental specialist to other patients who use Medicare or Medicaid. The penalties include civil monetary penalties of \$10,000 for each violation. An experienced healthcare compliance lawyer can explain the limitations of any type of incentive program.

There are exceptions to the Medicare incentive law that your lawyer can explain. These include:

- Some inexpensive gifts with limited value
- Some items or services that fit within the statutory exceptions:
 - Waivers of cost-sharing amounts based on financial need
 - Properly disclosed copayment differentials in health plans
 - Incentives to promote the delivery of certain preventive care services
 - Any practice permitted under the federal Anti-Kickback statute pursuant to 42 CFR 1001.952
 - Waivers of hospital outpatient copayments in excess of the minimum copayment amounts.

A skilled California healthcare lawyer will explain whether any of the referrals, incentives, or other transactions that may be permissible under a federal law exception or safe harbor – violate any California laws.

Additional dental care compliance issues

Some of the many other healthcare compliance issues dental practitioners need to review with a seasoned healthcare law are:

FDA violations

The Food and Drug Administration regulates:

- Drugs
- Medical Devices
- Food and nutritional products
- Cosmetic products
- Other products

The regulations include determinations about:

- Whether the products are adulterated or misbranded
- Current good manufacturing compliance
- Introduction of unapproved drugs into interstate commerce
- Other regulations

Dentists, orthodontists, and other health practitioners need to understand how FDA regulations apply to their practice. This understanding applies to different parts of their practice such as:

- The drugs, medical devices, and other products dentists use for their patients.
- The statements dentists make online and offline about the merits of any of these products to help patients with their oral health problems.

FTC violations

The Federal Trade Commission monitors the representations dental practitioners and dental supply companies make about the services and products they perform or use. These days, most dentists use websites, social media, and print marketing to help promote their practice. The FTC has the authority to review your marketing and branding. If the FTC believes your promotions violate the Federal Trade Commission Act and FTC regulations or rules, the FTC can send a warning letter and take other appropriate action.

The corporate practice of medicine

In California, decisions about the practice of medicine (including dentistry) must be made by the physicians and not by the business. In California, a medical corporation can be formed by complying with the California Moscone-Knox Professional Corporation Act. The medical corporation is a separate legal entity that must be owned by one or more physicians. Non-physicians can have a minority stake in a professional medical corporation.

Dentists can also practice as sole proprietors or in partnership with other dentists. An experienced healthcare lawyer can explain the pros and cons of each type of business structure.

The unauthorized practice of medicine

Dentists need to ensure they fully understand what tasks dentists can assign to their staff, which tasks dentists must perform themselves, and which tasks staff members can perform under their direct supervision.

Dentists must also ensure that they and the people the dentists work with are properly certified and their continuing medical education requirements are being met.

Generally, the Dental Board of California licenses and regulates over 100,000 dentists, registered dental assistants, and registered dental assistants in extended functions (RDAEF). The Board *"has the responsibility for setting the duties and functions of unlicensed dental assistants."*

Dentists, like other physicians, need to understand how Stark Law and the Anti-Kickback Statute apply to their practice and business relationships. Dentists need to understand their HIPAA compliance duties, and many other compliance issues such as FDA requirements, FTC requirements, and various California laws.

Doctors and medical practices should contact Cohen Healthcare Law Group, PC to discuss HIPAA and other laws that affect vaccination and other health records. Our experienced healthcare attorneys help healthcare providers establish HIPAA compliance protocols.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.