Corporate Practice of Medicine & Anti-Kickback / Fee-Splitting Rules: Deep Down the Regulatory Rabbit Hole

Many healthcare ventures seek to avoid corporate practice of medicine (or **psychology**) and fee-splitting violations, but they need to first understand how deeply down the rabbit hole these prohibitions go. This is a quick primer on how corporate practice of medicine and anti-kickback / fee-splitting rules can impact your healthcare venture. Although we focus on California, corporate practice prohibitions exist in many states, and vary by state.

For legal counsel to properly **structure** your venture, contact our healthcare attorneys.

Corporate Practice of Medicine

A. Unlicensed Practice and Corporate Practice Violations

Corporate Practice of Medicine is a variation of the statutory prohibition against unlicensed practice of medicine. In some states, the prohibition against CPM is created by statute; in other states, the prohibition is established through common law, or derives from the state's medical practice act, or is suggested by an Attorney General ("AG") opinion.

California law provides that an individual practices "medicine" when he or she:[1]
practices or attempts to practice, or … advertises or holds himself or herself out as practicing, any system or mode of treating the sick or afflicted in this state, or … diagnoses, treats, operates for, or prescribes for any ailment, blemish, deformity, disease, disfigurement, disorder, injury, or other physical or mental condition of any person.

The California Medical Board ("CMB") has a webpage on CPM, and aggressively enforces CPM violations. CMB cites the statute above regarding unlicensed practice, as well as the prohibition against corporations having professional rights, privileges, or powers.[2]

In California, the prohibition against corporate practice of medicine, imposes strict rules on contractual arrangements between physicians and non-physicians. One of the purposes of the CPM doctrine is to separate medical from business decision-making. Under this doctrine, **neither non-physicians nor lay corporations (corporations that are not medical professional corporations) nor limited liability companies (LLC) may contract to provide medical services. Nor may they contract with a physician to have the physician provide medical services, either as an employee or an independent contractor**.

In addition, California law places limits on the activities of non-medical corporations and LLCs managing health care practices, so as to ensure that such companies do not engage in clinical decision-making.

For example, the California Medical Board states that the following health care decisions should be made by a California-licensed physician and would constitute the unlicensed practice of medicine if performed by an unlicensed person:

- Determining what diagnostic tests are appropriate for a particular condition.
- Determining the need for referrals to, or consultation with, another physician/specialist.
- Responsibility for the ultimate overall care of the patient, including treatment options available to the patient.
- Determining how many patients a physician must see in a given period of time or how many hours a physician must work.

Recently, CMB has paid particular attention to medical spas and other ventures that can raise unlicensed practice and CPM issues.[3] For example, in *The Accusation Against Joseph F. Basile, M.D.*, CMB found that the licensed physician had aided and abetted unlicensed medical practice, when he permitted his wife (a non-licensee) to provide laser services to patients in a vein and cosmetic enhancement center that she owned, where the physician acted as "Medical Director."

Among other things, CMB rejected the contention that the physician's wife was acting as a "medical assistant," since the physician was not always physically presented when his wife administered intense pulse light (IPL) and laser treatments to patients; further, although it was the physician who "obtained patient histories, performed physical examinations, determined whether patients were appropriate candidates for treatment and who determined appropriate machine settings," the wife solely owned "The Vein & Cosmetic Enhancement Center." CMB noted:

It was her business. Importantly, the treatment was not ancillary to respondent's [*i.e.*, the physician's] workup or diagnosis of a patient's condition. Instead, it was the primary treatment mode sought by patients seeking removal of unsightly varicose veins or other cosmetic blemishes….. When … [the wife] provided IPL/laser treatment to patients, particularly when respondent was absent from the facility, she was not performing adjunctive services for respond. She was engaged in the unlicensed practice of medicine.

CMB went on to differentiate the wife's legally impermissible activities, from those "technical supportive services" legally permissible to medical assistants.

Although medical spas have been the particular targets of enforcement by CMB of late, due to rampant abuses with regard to unlicensed practice and lack of medical supervision, CMB does scrutinize arrangements more generally between LLCs and physicians as they raise similar issues.

For example, CMB also notes in The Bottom Line: The Business of Medicine—Medical Spasthat Business & Professions Code, Section 2272 requires advertising for an enterprise such as a medical spa, which offers medical services, to include the physician's name or the name for which the physician has a fictitious name permit; and notes that California law prohibits many advertising practices currently being used (including "discount or 'bait and switch' promotions").[4] Further, CMB cautions that the "clients" are the physician's patients, and must be treated as such—not as those of the non-physician entity.

B. MSO Model

We advise our non-physician clients in California that because of the CPM doctrine, and anti-kickback/fee-splitting rules, they cannot own a medical clinic or hire physicians.

However, they can own a management entity which can serve as an administrative and non-medical, management services organization ("MSO") for the clinic or medical practice, which is frequently organized as a professional medical corporation ("PMC").

In this model, the MSO contracts with the PMC so that the PMC agrees to provide professional services, and the MSO agrees to provide administrative and management services, such as:

- front desk, receptionist, and scheduling
- advertising and marketing
- sublease space and/or provide equipment (each under a written lease or management agreement with the PMC)
- book-keeping
- billing and collecting on behalf of the PMC.

All of these services are subject to applicable legal requirements (including more specific CPM prohibitions), and rules relevant to billing and collecting, and would require specific contractual provisions between the PMC and the MSO.

With respect to the MSO, CMB still imposes constraints through its interpretation of California law and strong enforcement posture. CMB on its webpage on CPM has noted that, the following "business" or "management" decisions and activities, resulting in control over the physician's practice of medicine, should be made by a licensed California physician and not by an unlicensed person or entity:

- Ownership is an indicator of control of a patient's medical records, including determining the contents thereof, and should be retained by a California-licensed physician.
- Selection, hiring/firing (as it relates to clinical competency or proficiency) of physicians, allied health staff and medical assistants.
- Setting the parameters under which the physician will enter into contractual relationships with third-party payers.
- Decisions regarding coding and billing procedures for patient care services.
- Approving of the selection of medical equipment and medical supplies for the medical practice.

CMB further states:

The types of decisions and activities described above cannot be delegated to an unlicensed person, including (for example) management service organizations. While a physician may consult with unlicensed persons in making the "business" or "management" decisions described above, the physician must retain the ultimate responsibility for, or approval of, those decisions.

According to CMB, the following types of medical practice ownership and operating structures also are prohibited:

- Non-physicians owning or operating a business that offers patient evaluation, diagnosis, care and/or treatment.
- Physician(s) operating a medical practice as a limited liability company, a limited liability partnership, or a general corporation.
- Management service organizations arranging for, advertising, or providing medical services rather than only providing administrative staff and services for a physician's medical practice (non-physician exercising controls over a physician's medical practice, even where physicians own and operate the business).
- A physician acting as "medical director" when the physician does not own the practice. For example, a business offering spa treatments that include medical procedures such as Botox injections, laser hair removal, and medical microdermabrasion, that contracts with or hires a physician as its "medical director."

In 2000, the California AG issued an opinion that a proposed agreement where the MSO would charge a management fee to a labor union, in exchange for the MSO arranging to "select, schedule, secure, and pay for radiology services ordered by the union's physician for union members," would violate CPM.[5] The AG stated:
The activities to be performed by the MSO would include selected a radiology site with the appropriate imaging equipment and qualified operators of the equipment, as well as selected a qualified and duly licensed radiologist to view the films and prepare an interpretive report…

We believe that the selection of a radiology site with appropriate equipment and operational personnel best suited for the performance of a diagnostic radiology study of a patient's particular disorder, as well as the selection of a qualified radiologist to

view and interpret the films, would involve the exercise of professional judgment and evaluation as part of the practice of medicine.

As suggested, CPM issues frequently overlap with kickback and fee-splitting concerns. As the California AG noted in the above opinion:

In addition to the selection, scheduling, and securing of the technical and professional aspects of the radiology services to be rendered, the MSO would pay for the radiology services and profit by adding a fee for its own management services. This financial aspect of the arrangement would be a further intrusion into the relationship between the physician and the patient.

The California AG also noted that the MSO would not qualify as a health care service plan under the Knox-Keene Health Care Service Plan Act of 1974. The California AG did not reach the question as to whether the proposed arrangement would violate H&S 445 (prohibiting referrals for profit to any physician or health-related facility), but presumably, it would, if the AG found a B&P 650 violation.

In addition to the above concerns, compensation arrangements between the MSO and the PMC must be for fair market value. Otherwise, the arrangements could conceivably be seen as creating an unlawful inducement to refer patients (*i.e.*, a kickback or fee-splitting). For this reason, with the MSO model, we advise retaining a backup spreadsheet that **justifies FMV for each management service rendered**.
Under B&P 650(b), the management fee must be:

(1) For services other than the referral of patients—*i.e.*, not an inducement to refer patients to those physicians or the PMC;

(2) Based on a percentage of gross revenue or similar type of contractual arrangement; and

(3) Commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer.

As well, out of an abundance of precaution, it is prudent to comply with the federal safe harbor for remuneration from an entity under a personal service arrangement or management contract. This safe harbor requires the following:

(1) the management agreement covers all the services the manager provides for the term of the agreement and specifies those services;

(2) the agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;

(3) the term of the agreement is for at least one year;

(4) the aggregate compensation paid to the manager over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties;

(5) the services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; and

(6) the aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Even if the safe harbor does not apply because no Medicare/Medicaid services are being provided, compliance with the safe harbor is advisable to bolster the argument that the arrangement is defensible..

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[1] Cal. Bus. & Prof. Code, §2052(a).
[2] Cal. Bus. & Prof. Code, Section 2400.

[3] See generally, CMB, The Bottom Line: The Business of Medicine—Medical Spas.
[4] See B&P, Section 651. We recommend legal review of all advertising associated with this project. In addition, note that other statutes (such as B&P 17200, prohibiting unfair business practices), can be brought to bear on business arrangements that enforcement authorities find questionable.
[5] 83 Op. Cal. Atty. Gen. 170 (No. 00-206).

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