

## Are physician online dietary supplement sales, kickbacks or fee-splitting?

March 31, 2016

By Michael H. Cohen

---

Are physician online dietary supplement sales, kickbacks or fee-splitting?

### The Challenge of Physician Online Dietary Supplement Sales

Can physicians, chiropractors, acupuncturists, and other healthcare licensees create a legally defensible contractual arrangement with a dietary supplement manufacturer, in which the healthcare clinician receives a discount, rebate, or commission when referring a patient for online purchase of the manufacturer's dietary supplements?

Let's take Singularity Supplements, a fictional dietary supplement manufacturer, and Dr. Bob, a physician who wants to sign up for Singularity's rebate program.

Singularity Supplements comes to our law office with an online program for licensed healthcare practitioners. The practitioner gets his or her own webpage which is doubly branded for the practitioner and for Singularity Supplements.

This means that once Dr. Bob signs up, whenever Dr. Bob sends a patient to Dr. Bob's Singularity Supplements website and the patient purchases supplements recommended by Dr. Bob, Singularity Supplements gives Dr. Bob a 25% rebate on the total retail purchase. Dr. Bob can then either pocket the 25%, or give it back to the patient. Either way, Singularity Supplements ships the dietary supplements to the patient and sends the check to Dr. Bob (or makes a direct deposit in his account).

This is a very common arrangement in the dietary supplements industry; but is it legal?

### Self-Referral, Anti-Kickback, & Fee-Splitting Issues

We talk a lot about self-referral, anti-kickback, and fee-splitting on this blog.

While there are federal prohibitions against self-referral ("Stark") and kickbacks, in general we are only looking at state law, because by and large, sales of dietary supplements are not reimbursed by Medicare or Medicaid. Every state has its own statutes and regulations, but there are some commonalities.

In general:

- *Fee-splitting* refers to a situation in which a physician literally splits his or her fee with a non-physician. For example, the doctor gets \$100 for a visit and gives you \$50 for referring the patient.

- *Self-referral* refers to a situation in which the physician refers the patient, for another healthcare service in which the physician has a financial interest. For example, your doctor sends you for lab tests where he or she owns the laboratory. Some types of self-referral (usually for what are known as “designated health services” or DHS) are prohibited, whereas others are allowed but require a disclosure of financial interest by the physician. There are both federal and state law prohibitions that vary in significant detail as to what activities and what streams of payment are a violation.
- A *kickback* refers to a situation where the physician pays, or receives, compensation in exchange for a referral. In the fee-splitting scenario, for example, the physician is paying for the referral. This can be a federal violation where federal payment is involved, and a violation of state statutes, which also vary in significant detail. Some state statutes speak to “brokering” or “steering” patients.

In addition to these rules, some states have:

- Prohibitions against “patient brokering” (for example, Florida), or against “steering” patients to medical centers for a profit
- Prohibitions against exploiting patients for financial gain (for example, in Michigan, promotion for personal gain of an unnecessary service).

Some states limit the prohibition explicitly to medical services, not goods; others, to “medical” goods but not services; and others, to goods and services reimbursed by private insurance.

Some states extend their prohibitions to all licensed healthcare practitioners, whereas others only speak to violations by medical doctors.

#### AMA and Federation of State Medical Boards Weigh in *Against* Physician Conflicts of Interest

The AMA and Federation of State Medical Boards generally do not approve of in-office sales by physicians of health products.

In Opinion 8.063 (Sale of Health-Related Products from Physicians’ Office), the American Medical Association wrote:

In-office sale of health-related products by physicians presents a financial conflict of interest, risks placing undue pressure on the patient, and threatens to erode patient trust and undermine the primary obligation of physicians to serve the interests of their patients before their own.

The AMA warned that physicians “should not sell any health-related products whose claims of benefit lack scientific validity.” Further, due to the “risk of exploitation,” AMA noted that physicians should:

- Limit sales to products that serve the immediate and pressing needs of their patients.
- Distribute other health-related products to their patients free of charge or at cost, in order to make useful products readily available to their patients.
- Disclose fully the nature of their financial arrangement with a manufacturer or supplier to sell health-related products. Disclosure includes informing patients of financial interests as well as about the availability of the product or other equivalent products elsewhere.
- Not participate in exclusive distributorships of health-related products which are available only through physicians’ offices.

The AMA noted that such guidelines also apply to sales through websites.

The Federation of State Medical Boards (FSMB), in its [Model Guidelines for the Use of Complementary and Alternative](#)

Therapies in Medical Practice, also addresses sale of goods from physician offices.

FSMB similarly warns about the “potential for patient exploitation” and states that “physicians should not sell ... health-related products or engage in exclusive distributorships and/or personal branding.”

Further, physicians should “provide a disclosure statement with the sale of any goods, informing patients of their financial interest.”

#### The Somewhat Concerning Case of *Charell v. Gonzales*

In this case, a New York trial court reviewed a jury verdict of negligence against a physician who incorporated nutritional advice into cancer care. The court also reviewed the jury’s punitive damages award to see if it was appropriate.

The court concluded that the punitive damages were justified *because* the physician’s:

practice of prescribing nutrition as a cure was designed to enable companies in which he had a financial interest to sell product. While there was evidence offered by the defendant to the contrary, the jury was entitled to find that defendant’s intent in dealing with plaintiff was motivated by greed and that he was reckless in his care of her.

As it turns out, the appellate court vacated the award for punitive damages after finding that defendant’s conduct was neither grossly dishonest, or indifferent to patient care.

#### Are Physician Dietary Supplement Sales Covered by Insurance

The *Charell* case is concerning to practitioners who have a financial stake in sales of supplements, because here the financial stake allowed the Court to label the physician not only negligent, but worse—“motivated by greed” and “reckless.”

Punitive damages are designed to punish the defendant, and thus are different from damages for negligence, which are only meant to be compensatory.

As well, a physician’s medical malpractice insurance may not necessarily cover punitive damages — or even nutritional recommendations or those involving dietary supplements.

If in doubt, it’s best to check in writing with your insurance carrier.

#### The Side Telemedicine Issue

If Dr. Bob makes his recommendations to his patient while the patient is out of the state in which Dr. Bob’s practice (i.e., Dr. Bob is in the “home” state in this scenario, and his patient is in the “remote” state), then Dr. Bob might be viewed as practicing in the “remote” state.

While some states provide allowances for temporary consultations while the patient is visiting the remote state, other more aggressive states might conclude that in recommending dietary supplements to a patient who is traveling through or located in a remote state, Dr. Bob is “prescribing” in the remote state. Typically, prescribing without an in-person, good faith exam, is unlawful.

#### Standard of Care Concern

If dietary supplements and nutritional therapies are not widely accepted as the (or part of the) course of treatment, there is a

risk that enforcement authorities could find a standard of care violation.

As *Charell* suggests, the legal ante gets upped if the practitioner also made a profit off a therapeutic recommendation that was non-standard or outside conventional medical bounds.

#### Some On-Point Legal Authority

California has an Attorney General opinion from 2001, that provides some sense as to how a clinician's financial interest in dietary supplements could be perceived.

In this situation (Op.Atty.Gen. No. 00-1002 (February 1, 2001), 2001 WL 117913), the Attorney General found that chiropractors are prohibited, under the terms of Business and Professions Code section 650, from participating in an Internet marketing plan in which they agree to promote the naturopathic products of an Internet company and to refer their patients to the company's website in exchange for fees of 20 percent of the price of the products purchased by their patients from the company's website.

There is a temptation to dismiss this opinion as reflective of the early, wild West days of the Internet. However, it's still resonating out there, unless and until the AG offers a different view.

#### Some Suggestions

The AMA and FSMB opinions make clear that they expect physicians to follow certain guidelines, including these:

- Physicians have a burden to justify the scientific and medical validity of their recommendations for dietary supplements.
- Physicians should fully disclose their financial interest in arrangements with dietary supplement manufacturers.

Physicians risk malpractice liability, and medical board discipline, when they run afoul of these kinds of parameters.

There are also state rules prohibiting kickbacks and fee-splitting to consider. These can also impact dietary supplement manufacturers and distributors who create and promote these kinds of programs. These laws can be very broad yet tough.

- For example, California Business and Professions Code, Section 650(a), prohibits a physician from receiving any "rebate" or "commission" as "compensation for referring patients...to any person."
- Similarly, in New York, a physician may not receive any rebate or commission "in connection with the furnishing of professional care or service." This prohibition is amplified by prohibitions on: (1) promoting the sale of services or goods for financial gain; (2) receiving any fee in exchange for "the referral of a patient;" (3) permitting any person to share in the fee for professional services; or (4) ordering unwarranted treatment.
- New Jersey limited a physician's markup to cost plus 10% to cover administrative expense. This was changed by Assembly Bill 4133.

Self-referral laws are often less critical, because they frequently focus only on certain designated health services set out in the governing statute — for example, referrals to clinical laboratories or for physical therapy; dietary supplements usually are not included.

- However, such statutes may require that physicians *disclose* their financial interest in the supplements when directing the patient to a website where the clinician makes a profit.

One option that a Singularity Supplements might consider is to restructure its program as follows.

Dr. Bob purchases, say, \$100 retail worth of dietary supplements from Singularity Supplements at a wholesale price of \$60, which is 40% off the retail price. Singularity Supplements charges Dr. Bob 25% of the retail price (\$25) for the Website platform, and for the fulfillment / drop-ship / back-office function. Since Dr. Bob has bought \$100 worth at a wholesale price of \$60, and has paid \$25 for platform and back-office services, he effectively earns \$35.

The argument to enforcement authorities would be that the \$35, rather than being a kickback from Singularity Supplements to Dr. Bob for referring the patient, in fact represents the difference between wholesale and retail, less the admin charges at fair market value.

Those charges have to be at fair market value (FMV). (And in New Jersey, the total profit to Dr. Bob cannot exceed \$10.)

Ideally, this can be worked out so that Dr. Bob does not have to purchase physical inventory, and so that the patient's payment flows first through Dr. Bob's account and then from Dr. Bob's account to Singularity Supplements, as otherwise it appears as if Singularity Supplements is paying Dr. Bob a commission.

Dr. Bob should disclose his financial interest at the time he sends the patient to the co-branded Webpage for purchase of supplements.

A Call to Action!

If you are a dietary supplement manufacturer or distributor with a rebate program for physicians, chiropractors, or other healthcare providers who direct patients to buy dietary supplements from your online store, or if you are such a practitioner, [contact us](#). We can provide legal counsel tailored to your situation.

Or, if you'd simply like more information, search this blog for more posts about dietary supplement sales.

[Contact](#) our [healthcare law](#) and [FDA attorneys](#) for legal advice relevant to your healthcare venture.