

Physician Sale of Dietary Supplements – Legal and Regulatory Restrictions

January 11, 2013

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Note that rules are always changing and these particular limits may have been modified.

Some states restrict the markup a physician can have on sales of dietary supplements. For example, New Jersey law has some relevant law.

Very generally, New Jersey law provides for restrictions on referrals of patients where the practitioner has a financial interest. Specifically:^[1]

a. A practitioner shall not refer a patient or direct an employee of the practitioner to refer a patient to a health care service in which the practitioner, or the practitioner's immediate family, or the practitioner in combination with the practitioner's immediate family has a significant beneficial interest.... (emphasis added)

b. If a practitioner is permitted to refer a patient to a health care service pursuant to this section, the practitioner shall provide the patient with a written disclosure form, prepared pursuant to section 3 of P.L.1989, c. 19 (C.45:9-22.6), and post a copy of this disclosure form in a conspicuous public place in the practitioner's office.

c. The restrictions on referral of patients established in this section shall not apply to:

(1) medical treatment or a procedure that is provided at the practitioner's medical office and for which a bill is issued directly in the name of the practitioner or the practitioner's medical office....

Relevant definitions are as follows:^[2]

"Health care service" means a business entity which provides on an inpatient or outpatient basis: testing for or diagnosis or treatment of human disease or dysfunction; or dispensing of drugs or medical devices for the treatment of human disease or dysfunction. Health care service includes, but is not limited to, a bioanalytical laboratory, pharmacy, home health care agency, rehabilitation facility, nursing home, hospital, or a facility which provides radiological or other diagnostic imagery services, physical therapy, ambulatory surgery, or ophthalmic services. (emphasis added)

"Immediate family" means the practitioner's spouse and children, the practitioner's siblings and parents, the practitioner's spouse's siblings and parents, and the spouses of the practitioner's children.

“Practitioner” means a physician, chiropractor or podiatrist licensed pursuant to Title 45 of the Revised Statutes.

“Significant beneficial interest” means any financial interest; but does not include ownership of a building wherein the space is leased to a person at the prevailing rate under a straight lease agreement, or any interest held in publicly traded securities.

The written disclosure form:[3]

shall be prescribed by regulation of the State Board of Medical Examiners. In addition to such other information as the board determines necessary, the disclosure shall inform the patient whether any services or facility fees associated with the referral will be considered to be, and reimbursed at, an “out-of-network” level by the patient’s insurance carrier or other third party payer.

Regulations of the New Jersey State Board of Medical Examiners, published in the New Jersey Administrative Code, further elaborate on these requirements, in NJCA §13:35-6.17 Professional fees and investments, prohibition of kickbacks:[4]

(a) For the purposes of this rule, the following words and terms shall have the following meanings:

1. “Health care service” means a business entity which provides on an in-patient or out-patient basis: testing for or diagnosis or treatment of human disease or dysfunction or dispensing of drugs or medical devices for the treatment of human disease or dysfunction. Health care service includes, but is not limited to, a bioanalytical laboratory, pharmacy, home health care agency, home infusion therapy company, rehabilitation facility, nursing home, hospital, or a facility which provides radiologic or other diagnostic imaging services, physical therapy, ambulatory surgery, or ophthalmic services.

2. “Financial interest” means a monetary interest of any amount held by a practitioner personally or through immediate family, as defined herein, in a health care service to which the practitioner’s patients are referred. It includes the offer or receipt, directly or indirectly, by the practitioner or immediate family of anything of more than negligible value as a result of a patient’s purchase of a prescribed service, goods or device from the person or entity providing this. Except as set forth in (a)2i through vii below, “financial interest” includes a licensee’s financial interest in a contractual arrangement with a licensed health care facility (such as a hospital, nursing home or clinic, etc.), whereby the licensee agrees to provide health care services on referral, for example, cardiac or radiologic diagnostic testing, to patients including those receiving Emergency Room care or inpatients or outpatients of the health care facility....

3. “Immediate family” means the practitioner’s spouse and children, the practitioner’s siblings and parents, the practitioner’s spouse’s siblings and parents, and the spouses of the practitioner’s children.

4. “Practitioner” means a physician, podiatrist, bioanalytical laboratory director or specialty laboratory director, acupuncturist, midwife, certified nurse midwife, physician assistant and all other categories of licensee now or henceforth under the jurisdiction of the State Board of Medical Examiners.

5. “Significant beneficial interest” means any financial interest including an equity or ownership interest in a practice or in a commercial entity holding itself out as offering health care service as defined in (a)1 above. This interest does not, however, include ownership of a building or component thereof wherein the space is leased, in writing, to a person or entity at the prevailing rate under a straight lease agreement (that is, a fixed fee for a fixed term), or any interest held in publicly traded securities....

(b) A practitioner shall not refer a patient or direct an employee of the practitioner to refer a patient to a health care service in which the practitioner or the practitioner’s immediate family, or the practitioner in combination with the practitioner’s immediate family, has a significant beneficial interest.... Disclosure shall be made by the practitioner in ways appropriate to the professional circumstances including conspicuous posting of a written disclosure form prepared as set forth below, at least 8 1/2 by 11 inches in size, in the practitioner’s waiting room in all office locations. The patient shall also be provided with a

personal copy of the notice. The notice format shall be as follows:

Public law/rule of the State of New Jersey/Board of Medical Examiners mandates that a physician, podiatrist and all other licensees of the Board of Medical Examiners inform patients of any significant financial interest held in a health care service. Accordingly, take notice that practitioners in this office do have a financial interest in the following health care service(s) to which patients are referred:

(LIST APPLICABLE HEALTH CARE SERVICES) You may, of course, seek treatment at a health care service provider of your own choice. A listing of alternative health care service providers can be found in the classified section of your telephone directory under the appropriate heading.

1. In any inquiry regarding the applicability of the financial disclosure provisions of this rule, including the holding of a significant beneficial interest or exemption therefrom, the Board may require a Board licensee to submit financial and familial information sufficient to determine the financial interest in an investment....

4. The restrictions on referral of patients established in this subsection shall not apply to:

i. A health care service that is provided at the practitioner's medical office for which the patient is billed directly by and in the practitioner's name....

(c) The following pertain to miscellaneous monetary arrangements:

1. A licensee shall not, directly or indirectly, give to or receive from any licensed or unlicensed source a gift of more than nominal (negligible) value, or any fee, commission, rebate or bonus or other compensation however denominated, which a reasonable person would recognize as having been given or received in appreciation for or to promote conduct by a licensee including: purchasing a medical product, ordering or promoting the sale or lease of a device or appliance or other prescribed item, prescribing any type of item or product for patient use or making or receiving a referral to or from another for professional services. For example, a licensee who refers a patient to a health care service (such as a cardiac rehabilitation service or a provider of durable medical equipment or a provider of testing services) shall not accept from nor give to the health care service a fee directly or indirectly in connection with the referral, whether denominated as a referral or prescription fee or consulting or supervision fee or space leasing in which to render the services (other than as permitted in (h) below), or by any other name, whether or not the licensee has a financial interest as defined in (a) above....

ii. This section shall be construed broadly to effectuate its remedial intent. It shall not, however, prohibit a flat-fee payment by a licensee for regular advertising services (including placement on a commercially-sponsored "referral list" of licensed health care providers). It shall not prohibit receipt of reasonable payment for bona fide participation as a speaker at a professional workshop or seminar nor attendance by non-faculty licensees at a continuing medical education program whereby in conformance with the guidelines of the Accreditation Council on Continuing Medical Education or the American Podiatric Medical Association commercial sources have been utilized in calculating the registration fees to be charged to all participants. It shall not prohibit receipt of normal, commercially reasonable discounts for volume purchases from vendors, nor prohibit compensation for the sale of medical equipment by a licensee of the Board, in the disclosed capacity of a salesman, to another licensed health care professional. It shall not prohibit a licensee's participation by permit in an FDA-approved research project.

2. A laboratory director licensee may bill either the patient or the prescribing physician who submits the specimen, as permitted by N.J.S.A. 45:1-10.

3. All other categories of licensees who bill for professional services shall submit the bill directly or via a named designee entity to the patient or patient representative if for treatment services, or to the recipient of the professional services in a non-patient capacity, as applicable.

4. A bill for services of members of a professional service corporation, or services of a physician's employees which have been rendered by licensed professionals authorized to provide services without medical supervision, shall identify the provider of

service by name and degree, as well as the name of the service entity (if different).

5. A licensee may bill for only the actual cost of prescribed professional/technical services (including, for example, laboratory services, radiologic and EKG consultation, fabrication of eyeglasses, orthotics, etc.) ordered by or through the licensee, with the patient's consent, provided that the name and address of the provider of the professional/technical services and the cost as billed to the licensee, are disclosed to the patient. A licensee may contract with and provide professional/technical services to the prescribing licensee, supplying the information necessary for incorporation in the bill prepared by the prescribing licensee to the patient.

(d) A licensee shall not charge for "free samples" or other similar items obtained by the licensee from any source.

(e) Acting within the scope of lawful practice, a licensee may offer to and provide to a patient medications, including a prescription drug or an over-the-counter preparation or vitamin or food supplement (emphasis added), but only in accordance with the requirements of P.L. 1991, c. 187, sec. 46 N.J.S.A. 45:9-22.11 and N.J.A.C. 13:35-7.^[5] A licensee may also offer to and provide to a patient, at fair market value, medical goods and devices such as hearing aids, eyeglasses, contact lenses, prosthetic devices, orthotics, etc.

1. Where items are prescribed by a licensee, and the consumer elects to fill the prescription elsewhere, the prescriber's obligation to the patient shall include, if requested by the patient, follow-up to ascertain that the item prescribed is appropriate and/or the fit is acceptable (for example, as in the prescribing of eyeglasses or external contact lenses), and that the result of the prescribed service is properly evaluated and integrated into the treatment plan for the patient.....

(j) A licensee having a significant beneficial interest, as defined in (a) above, in a health care service including a professional service corporation or a general business corporation (see N.J.A.C. 13:35-6.16(f)) shall notify the Board of such interest no later than February 18, 1993. Notice is not required for a practice conducted under the practitioner's own name.

Thus, it seems that New Jersey limits a physician's markup to cost plus 10% to cover administrative expense.

If you need legal counsel concerning sales of nutraceuticals or dietary supplements by a medical doctor, osteopathic physician, or other clinician, whether in New Jersey, New York, California, or elsewhere, contact an experienced healthcare lawyer for relevant legal and regulatory advice. The [Cohen Healthcare Law Group](#) counsels clinicians, medical and healthcare facilities, and healthcare business on dietary supplement legal and regulatory issues. Call us today.

[1] N.J.S.A. 45:9-22.5.

[2] N.J.S.A. 45:9-22.5.

[3] N.J.S.A. 45:9-22.6.

[4] [N.J.A.C. 13:35-6.17](#) (2012); see also the official New Jersey medical board's publication of these rules.

[5] 46 N.J.S.A. 45:9-22.11 provides that when a physician dispenses "medicines:" "The drugs or medicines shall be dispensed at or below the cost the physician has paid for the particular drug or medicine, plus an administrative cost not to exceed 10% of the cost of the drug or medicine."

N.J.A.C. 13:35-7 deals with prescription, administration, and dispensing of drugs. The subchapter defines "drug" as: "any article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to those sources, including, but not limited to, a controlled substance, a prescription legend drug, an over-the-counter preparation, **a vitamin or food supplement**, or any compounded combination

of any of the above....” N.J.A.C. 13:35-7.1.



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