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DOH GC Opinion No. 04-01
Ancillary Services in State Stark Law

Dear Ms. Kessler:

I am responding to your letter in which you sought clarification of the level of supervision required of a physician who employs a clinical laboratory technician, in order to meet the in-office ancillary services exception to the self-referral ban set forth at New York State's Public Health Law (PHL) § 238-a(2)(b). You asked how, since January 4, 2001, when the federal Department of Health and Human Services (HHS) reinterpreted the meaning of "directly supervised" in the so-called "Stark Law," codified at section 1877(b)(2) of the Social Security Act, 42 USC § 1395nn(b)(2), this Department (DOH) now interprets the meaning of "supervised" in PHL § 238-a(2)(b), the State counterpart of the Stark Law.

Federal and New York law each generally forbid a physician to refer a patient to a provider of clinical laboratory services, among others, with which the physician has a financial relationship. Among the exceptions to these prohibitions is one for certain in-office ancillary services provided personally by individuals who are supervised by the physician. Federal law says "directly supervised," while New York law simply says "supervised."

Before 2001, HHS interpreted "directly supervised" to require, for purposes of 42 USC § 1395nn(b)(2), a physician who is actually present in the office suite in which the services are being furnished, and who is immediately available to provide assistance and direction. See, 60 FR at 41961 through 41963 (August 14, 1995). During the same period, for purposes of PHL § 238-a(2)(b), DOH interpreted supervision of a shared laboratory to mean, direct supervision with the same meaning then given that term by HHS. See, June 5, 1996 opinion of DOH General Counsel.

Recently, HHS concluded that Congress in the Stark Law did not use the phrase "directly supervised" in any technical sense, and that Congress did not intend physicians to be present at all times that ancillary services were being performed. Rather, HHS reinterpreted "directly supervised" to mean, for purposes of 42 USC § 1395nn(b)(2), that the in-office ancillary services

exception supervision requirements will be satisfied if the level of supervision provided meets all applicable Medicare or Medicaid payment and coverage requirements. See, 66 FR at 885 through 887 (January 4, 2001).

For laboratory services, DOH will now follow the HHS determination that the in-office ancillary services exception to the supervision requirements should not be interpreted in any technical sense. Rather, in that context, the purpose of the state supervision requirement in PHL § 238-a(2)(b) is “to establish a nexus between the referring physician and the individual performing the ancillary services in order to limit the exception to services that are truly ‘ancillary’ to the referring physician’s medical practice.” See, 66 FR at 885 (January 4, 2001). Thus, in order to ensure that the ancillary services are truly subordinate to the services of the referring physician, the individual performing the ancillary services must be truly subordinate to the practitioner or group practice.

PHL § 238-a(2)(b) already requires that the supervised individual be “employed by such practitioner or group practice.” Generally, the legal relationship of employer and employee exists when the employer “has the right to control and direct the individual who performs the services, not only as to the result to be accomplished by the work but also as to the details and means by which that result is accomplished. That is, an employee is subject to the will and control of the employer not only as to what shall be done but how it shall be done. In this connection, it is not necessary that the employer actually direct or control the manner in which the services are performed; it is sufficient if he has the right to do so” (26 CFR 31.3121(d)-1(c); see also, 57 Fed. Reg. 8593 (March 11, 1992)).

In order to supervise the employee, the practitioner or one of the practitioners in the group practice must monitor the employee closely and frequently enough to be able to control and direct the details and means by which the employee furnishes the in-office ancillary services and to control what the employee will do and how he or she will do it. The supervisor would be present and immediately available to the extent necessary to ensure that the services the employee is furnishing are ancillary to the services of the referring practitioner.

Very truly yours,

Donald P. Berens, Jr.
General Counsel

cc: Betty Kusel