



Better Health Care for All Floridians

August 5, 2011 letter to laboratory directors regarding kickbacks in clinical laboratories:

Dear Laboratory Director:

The Agency has been advised that the regulations regarding kickbacks by clinical laboratories is not clearly understood. Pursuant to Section 483.245(1), Florida Statutes, "it is unlawful for any person to pay or receive any commission, bonus, kickback, or rebate or engage in any split-fee arrangement in any form whatsoever with any dialysis facility, physician, surgeon, organization, agency, or person, either directly or indirectly, for patients referred to a clinical laboratory licensed under this part." A kickback is one aspect of this statute. Rule 59A-7.020(14), Florida Administrative Code defines "kickback" for clinical laboratories:

59A-7.020(14) Kickback – a remuneration, payment back, or other inducement, direct or indirect, in cash or in kind, pursuant to an investment interest, compensation arrangement, or otherwise, made by any person as defined in Section 483.041(7), F.S., including any clinical laboratory as defined in Section 483.041(2), F.S., to any physician, surgeon, organization, agency, or person as an incentive or inducement to refer any individual or specimen to a laboratory licensed under Chapter 483, Part I, F.S., such as the following:

- (a) Provision of an actual payment or investment interest;
- (b) Rental of real estate or equipment where the lease agreement does not comply with the criteria set forth in Section 456.053, F.S.;
- (c) Provision of computer equipment and office supplies, except for those items, devices or supplies that are for the sole purpose of the following:
 1. Collecting, processing, storing and transporting specimens to the laboratory;
 2. Transmitting laboratory information to the laboratory; or
 3. Ordering or communicating laboratory tests or results and other patient information between the physician, surgeon, organization, agency, or person and the laboratory;

- (d) Removal and disposal of biomedical waste generated by the physician, surgeon, organization, agency, or person or any employees, representatives or agents of any such physician, surgeon, organization, agency, or person;
- (e) Provision of personal protection supplies and equipment, except that gloves are permitted to be provided;
- (f) Provision of test kits, systems or other laboratory supplies, except as provided in paragraph (c) above; or
- (g) Provision of personnel or assistance of any kind to perform any duties for the collection or processing of specimens. Such personnel or assistance is authorized to be provided on a temporary basis for the collection of specimens at a patient's residence. These collections must meet the requirements of Chapter 59A-7, F.A.C.

Although some examples of what constitutes a "kickback" under this rule are outlined in (a) through (g) of the rule, please be aware that this listing of examples is not exhaustive.

The Agency has issued two Final Order [see note below] related to this section of the rule regarding:

(f) Provision of test kits, systems or other laboratory supplies, except as provided in paragraph (c) above.

(g) Provision of personnel or assistance of any kind to perform any duties for the collection or processing of specimens. Such personnel or assistance is authorized to be provided on a temporary basis for the collection of specimens at a patient's residence. These collections must meet the requirements of Chapter 59A-7, F.A.C.

A copy of these Agency Final Orders is available at:

http://ahca.myflorida.com/mchq/health_facility_regulation/laboratory_licensure/TAP.shtml.

[and may also be accessed at:

- Final Order on 2008 Petition for Declaratory Statement: [2008 Final Order Dominion Diagnostics](#)
- Final Order on 2009 Petition for Waiver: [2009 Final Order DVA](#)]

Provision of Personnel

Generally, the collection of specimens by laboratory staff at physician's offices (or other organization referring for laboratory services) is not permissible unless such personnel services are paid appropriately for the service.

Paragraph (g) of 59A-7.020(14) addresses personnel to collect or process specimens and authorizes such personnel on a temporary basis at a patient's residence. A nursing home, assisted living facility, hospice inpatient house, intermediate care facility for the developmentally disabled, or another similar residential health care facility where a patient lives is considered the patient's residence as described in this paragraph. For example, sending a phlebotomist for the sole purpose of drawing blood such a residence would be permissible regardless of whether a contract exists between the laboratory and the health care facility, or if phlebotomist arrives regularly scheduled times, as long as the phlebotomist is only at the facility on a temporary basis.

Lease Arrangements

In a lease agreement in which a laboratory leases space from a physician or other organization referring for laboratory services, the lease must be for a commercially reasonable business purpose. For example, leased space adjacent to a physician's office must be open to other business of the laboratory to clearly serve an array of other physician or organization referrals. Such space is considered part of the laboratory licensed operation, and must be reported to the Agency and accessible for inspection as required by law. A lease entered into for the purpose of inducing referrals from the lessor is a kickback.

If you have questions about this Agency rule, please contact the Laboratory Unit at: 850.412.4500.

If you are aware or have reason to believe that a clinical laboratory is offering a kickback as defined under this rule, please call the Agency toll-free: 1-**888-419-3456**.

Note: Petition of Declaratory Statement under AHCA case number 2008008228 and Petition for Waiver under AHCA case number 2009000045