

STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION

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AGENCY CLERK

2008 JUL -7 A 11: 59

In Re:

FRAES No.: 2008004635

**Petition for Declaratory Statement of:
American Health Associates Clinical Laboratory, Inc.**

DECLARATORY STATEMENT

THIS CAUSE came on for consideration before the Agency for Health Care Administration on the Petition for Declaratory Statement of American Health Associates Clinical Laboratory, Inc. ("Petitioner" or "American Health Lab") filed with the Agency for Health Care Administration ("Agency"), on April 7, 2008, pursuant to Section 120.565, Florida Statutes (2008), and Rules 28-105.001 and 28-105.002, Florida Administrative Code. Notice of the Petition for Declaratory Statement was published in the Florida Administrative Law Weekly at Volume 34, Number 17, Page 2253, April 25, 2008.

QUESTION PRESENTED

The Petitioner requests a declaratory statement determining, "...[W]hether a clinical laboratory that (1) offers discounts to SNFs [skilled nursing facilities] for ancillary laboratory services under Medicare Part A that exceed the laboratory's actual documented cost savings, and/or (2) offers discounted charges to SNFs for ancillary laboratory services under Medicare Part A that are below the laboratory's actual full loaded costs of providing services, would be considered by the Agency to be paying prohibited rebates to the SNFs if the laboratory receives referrals from the SNFs for the provision of undiscounted laboratory services to the SNFs' patients under Medicare Part B."¹

¹ Petitioner's Petition for Declaratory Statement before the Agency for Health Care Administration, at paragraph 20.

STATEMENT OF THE FACTS

1. The Petitioner alleges the following statement of facts in support its Petition, which the Agency assumes are correct for the purposes of this Declaratory Statement. See Fla. Admin. Code R. 28-105.003.

a. Petitioner is a clinical reference laboratory providing services to patients in skilled nursing facilities. The patients Petitioner serves are usually insured by Medicare Part A or Part B.

b. For Medicare Part A recipients, the SNF is paid a flat daily rate for most services including laboratory testing. Any outside vendors that provide ancillary services, such as laboratory testing, must be paid on behalf of the patient by the SNF from the fixed daily rate paid to the SNF from Medicare.

c. Medicare Part B may pay for some ancillary services and outside vendors bill Medicare directly for Part B recipients as is done for other third party payors such as Medicaid or a long term care insurer.

d. It has become a practice in the industry, and specifically in the Tampa-Sarasota and Miami-Palm Beach areas, for clinical laboratories to discount charges to SNFs for ancillary laboratory services provided to Medicare Part A patients of the SNF.

e. The discounts range from fifteen percent (15%) to sixty percent (60%) of the charges for the same services when the patient is not a Medicare Part A recipient. In some instances the laboratory enters into an agreement with the SNF for the payment of one dollar (\$1.00) per Medicare Part A patient, per day, for the provision of unlimited ancillary laboratory services to said patient. This "one dollar (\$1.00)" arrangement amounts to an eighty percent (80%) to ninety percent (90%) discount. Further, a number of laboratories do not charge SNFs for drawing blood or transporting specimens for

Medicare Part A recipients but do charge for these activities for patients under Medicare Part B.

f. Clinical laboratories that do not offer significant discounts for ancillary services for Medicare Part A patients in SNFs are at a disadvantage in the market place as these laboratories are less likely to receive referrals from SNFs for the provision of ancillary laboratory services under Medicare B.

g. In an effort to remain competitive, Petitioner is considering offering the aforementioned discounts to SNFs for Medicare Part A recipients but is concerned that said practice could be considered a violation of Section 483.245(1), Fla. Stat., and Rule 59A-7.037, Fla. Admin. Code by the Agency.

JURISDICTION

2. “Any substantially affected person may seek a declaratory statement regarding an agency’s opinion as to the applicability of a statutory provision, or of any rule or order of the agency, as it applies to the petitioner’s particular set of circumstances.” § 120.565, Fla. Stat. (2008). “A declaratory statement is a means for resolving a controversy or answering questions or doubts concerning the applicability of statutory provisions, rules, or orders over which the agency has authority. A petition for declaratory statement may be used to resolve questions or doubts as to how the statutes, rules, or orders may apply to the petitioner’s particular circumstances. A declaratory statement is not the appropriate means for determining the conduct of another person.” Fla. Admin. Code R. 28-105.001.

3. “The purpose of a declaratory statement is to address the applicability of a statutory provision or an order or rule of the agency in particular circumstances.” Chiles v. Department of State, Division of Elections, 711 So.2d 151, 154 (Fla. 1st DCA 1998). One benefit of a declaratory statement is that it helps “avoid costly administrative litigation by selecting the

proper course of action in advance.” National Association of Optometrists and Opticians v. Department of Health, Bd. of Optometry, 922 So.2d 1060, 1062 (Fla. 1st DCA 2006). It enables a party “to select a proper course of action in advance” of its actions, Novick v. Department of Health, Board of Medicine, 816 So.2d 1237, 1240 (Fla. 5th DCA 2002), and allows “the public to definitively resolve ambiguities of law arising in the conduct of their daily affairs or in the planning of their future affairs.” Department of Business and Professional Regulation, Division of Pari-Mutual Wagering v. Investment Corporation of Palm Beach, 747 So.2d 374, 382 (Fla. 1999).

4. The Agency is the state agency that licenses and regulates clinical laboratories in Florida under the Health Facility and Services Development Act and Health Care Licensing Procedures Act (Chapter 408, Part I, and Part II, Florida Statutes, respectively), the authorizing statutes and administrative rules for clinical laboratories (Chapter 483, Florida Statutes, and Chapter 59A-7, Florida Administrative Code). Further, the Agency is the state agency that licenses and regulates skilled nursing facilities in Florida under the Health Facility and Services Development Act and Health Care Licensing Procedures Act (Chapter 408, Part I, and Part II, Florida Statutes, respectively) and the authorizing statutes and administrative rules for skilled nursing facilities (Chapter 400, Part II, Florida Statutes, and Chapter 59A-4, Florida Administrative Code). The Agency has substantive jurisdiction over the statutes in question.

5. American Health Lab is licensed by the Agency under Chapter 483, Part I, and Chapter 408, Part II, Fla. Stat., as a clinical laboratory with its principal office in Miramar, Florida.

6. In the present case, the Petitioner has demonstrated an actual, present and practical need as well as a potential impact on its substantial interests to receive a declaratory statement from the Agency. Couch v. Dep’t of Health and Rehabilitative Services, 377 So.2d 32 (Fla. 1st

DCA 1979).

ANALYSIS

7. An analysis of the legal issues presented by Petitioner begins with a review of the following statutes and regulations as cited in the Petition for Declaratory Statement:

a. Section 483.245(1), Florida Statutes (2008):

(1) 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.

b. Rule 59A-7.037, Florida Administrative Code:

(1) No owner, director, administrator, physician, surgeon, consultant, employee, organization, agency, representative, or person either directly or indirectly, shall pay or receive any commission, bonus, kickback, rebate or gratuity or engage in any split fee arrangement in any form whatsoever for the referral of a patient. Any violation of Rule 59A-7.037, F.A.C., by a clinical laboratory or administrator, physician, surgeon, consultant, employee, organization, agency, representative, or person acting on behalf of the clinical laboratory will result in action by the agency under Section 483.221, F.S., up to and including revocation of the license of the clinical laboratory. In the case of any party or individual not licensed by the agency acting in violation of this Rule, a fine not exceeding \$1,000 shall be levied and, as applicable, the agency shall recommend that disciplinary action be taken by the entity responsible for licensure of such party or individual.

(2) No licensed practitioner of the healing arts or licensed facility is permitted to add to the price charged by any laboratory except for a service or handling charge representing a cost actually incurred as an item of expense. However, the licensed practitioner or licensed facility is entitled to fair compensation for all professional services rendered. The amount of the service or handling charge, if any, shall be set forth clearly in the bill to the patient.

(3) Each licensed laboratory shall develop a fee schedule for laboratory services which shall be available to the patient, the authorized person requesting the test or agency upon request and shall be subject to subsection 59A-7.037(2), F.A.C.

8. Due to the lack of judicial or administrative opinions that interpret Section 483.245, Florida Statutes, Petitioner turns to federal opinions that discuss and interpret the Federal Anti-Kickback Statute to provide examples and guidance to the Agency.

9. The Agency specifically declines to consider or interpret these Federal opinions and instead relies solely on state law.

10. The question Petitioner poses to the Agency speaks in terms of the contemplated activity potentially falling into the category of “prohibited rebates.”² The term “rebate” as used in Chapters 483 and 400 is not specifically defined by the legislature and, as such, “The plain meaning of the statutory language is the first consideration.” St. Petersburg Bank & Trust Co. v. Hamm, 414 So.2d 1071, 1073 (Fla. 1982).

11. The word rebate is defined as, “A deduction from an amount to be paid or a return of part of an amount given in payment.” *The American Heritage Dictionary of the English Language*, 4th ed. Boston: Houghton Mifflin, 2000 (emphasis added).

12. A reduction by laboratories of the amount charged to SNFs for ancillary laboratory services provided under Medicare Part A falls within the plain meaning of the term “rebate” as used in Section 483.245(1), Florida Statutes (2008). A reduction in the cost of the services for Medicare Part A recipients is a rebate as it is a “deduction from the amount to be paid” by a SNF to a laboratory for patient services. Rebates of any type, whether direct or indirect, for any patient referred to a clinical laboratory are unlawful under the statute and the implementing rule. Section 483.245(1), Florida Statutes (2008); Rule 59A-7.037, Florida Administrative Code. Under the language of 483.245(1) the additional element of providing services to Medicare Part B patients of the SNF at full cost is not needed to constitute a rebate.

13. The term “kickback” is not defined in Section 483.245 but is defined in the implementing rules for laboratories, specifically, Rule 59A-7.020(15), Florida Administrative

² The Agency acknowledges that “Rebates prohibited; penalties.—” is the title of Section 483.245, Florida Statutes and that Petitioner may be using “rebate” as a general means of referencing the section, however, a “rebate” is one of the arrangements prohibited by 483.245, and, as such, an analysis of the conduct under this term is still relevant.

Code. Although this definition is not included in the Petition it is relevant to this analysis and is as follows:

(15) 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 455.236, 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. Rule 59A-7.020(15), Florida Administrative Code.

14. Under the definition of "kickback" the conduct described in the Petition would again be considered prohibited by Section 483.245(1), Florida Statutes (2008).

15. Specifically, the reduction by a laboratory of the cost for ancillary laboratory services for Medicare Part A recipients of a SNF is a direct cash inducement (a reduction in the price for

services rendered by the laboratory), pursuant to a compensation agreement (the agreement between the laboratory and the SNF for payment for laboratory services) to an organization (SNF) as an incentive to refer a specimen to the laboratory (the specimen of the Medicare Part A patient and/or the Medicare Part B patient).

16. The following provisions, taken from Chapter 400, Part II, Florida Statutes, regarding skilled nursing facilities, while not referenced in the Petition, are also deemed relevant by the Agency to the question posed by Petitioner:

- a. Section 400.17, Florida Statutes (2008):

Bribes, kickbacks, certain solicitations prohibited.--

(1) As used in this section, the term:

(a) "Bribe" means any consideration corruptly given, received, promised, solicited, or offered to any individual with intent or purpose to influence the performance of any act or omission.

(b) "Kickback" means that part of the payment for items or services which is returned to the payor by the provider of such items or services with the intent or purpose to induce the payor to purchase the items or services from the provider.

(2) Whoever furnishes items or services directly or indirectly to a nursing home resident and solicits, offers, or receives any:

(a) Kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment; or

(b) Return of part of an amount given in payment for referring any such individual to another person for the furnishing of such items or services; is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or by fine not exceeding \$5,000, or both.

(3) No person shall, in connection with the solicitation of contributions to nursing homes, willfully misrepresent or mislead anyone, by any manner, means, practice, or device whatsoever, to believe that the receipts of such solicitation will be used for charitable purposes, if such is not the fact.

(4) Solicitation of contributions of any kind in a threatening, coercive, or unduly forceful manner by or on behalf of a nursing home by any agent, employee, owner, or representative of a nursing home shall be grounds for denial, suspension, or revocation of the license for any nursing home on behalf of which such contributions were solicited.

(5) The admission, maintenance, or treatment of a nursing home resident whose care is supported in whole or in part by state funds may not be made conditional upon the receipt of any manner of contribution or donation from any person. However, this may not be construed to prohibit the offer or receipt of contributions or donations to a nursing home which are not related to the care of a specific resident. Contributions solicited or received in violation of this subsection shall be grounds for denial, suspension, or revocation of a license for any nursing home on behalf of which such contributions were solicited.

b. Section 400.176, Florida Statutes (2008):

(1) 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 physician, surgeon, organization, agency, or person, either directly or indirectly, for residents referred to a nursing home licensed under this part.

17. Chapters 483 and 400 of the Florida Statutes contain identical language regarding the prohibition of bonuses, kickbacks, commissions and split-fee arrangements for the referral of patients/residents to the laboratory or SNF by any individual or entity. See Sections 483.245(1) and 400.176, Florida Statutes (2008). Chapter 400, Florida Statutes, also contains the section cited above which provides definitions of relevant terms and additional prohibitions which apply in the SNF/nursing home setting.

18. Specifically, Section 400.17, Florida Statutes (2008), applies to SNFs and all individuals or entities that provide services to the residents of these facilities and is therefore directly applicable to the questions presented in the instant Petition.

19. The conduct described by Petitioner also potentially falls within the definition of "bribe" as expressed in Section 400.17, Florida Statutes (2008). A reduction in the cost of the services for Medicare Part A recipients is "consideration" and if said consideration is offered with the intent of influencing the performance of an act, i.e. the referral of Medicare Part B patients of the SNF to the laboratory, then the action could fall within the statutory definition of a bribe under Section 400.17.

20. Section 400.17 goes on to mandate, "Whoever furnishes items or services directly or indirectly to a nursing home resident and solicits, offers, or receives any (a) Kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment; or (b) Return of part of an amount given in payment for referring any such individual to another person for the furnishing of such items or services; is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or by fine not exceeding \$5,000, or both." Section 400.17(2), Florida Statutes (2008).

21. Under Section 483.245(1), Florida Statutes, and Rule 59A-7.037, Florida Administrative Code, a laboratory is prohibited from offering discounts to Medicare Part A patients of a SNF as posed by the Petitioner as said discounts would constitute both a rebate and a kickback. Under the Rule, the Agency must act to prevent the activities described in the Petition. Effective and efficient enforcement of the Rule by the Agency will be best achieved through utilization of the Agency's complaint hotline by those within the industry that are aware of such violations.

22. Under Section 400.17, Florida Statutes, a laboratory is prohibited from offering the discounts described in the Petition when the discount is offered with the intent to influence the performance of an act, such as the referral by the SNF of Medicare Part B patients to the laboratory as alluded to in the Petition.

DECLARATION

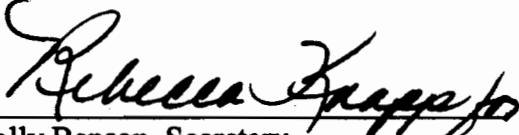
1. Based upon the statement of facts set forth in the Petition and the application of the above cited law to these facts, the Agency declares that clinical laboratories that reduce the fee charged to skilled nursing facilities for ancillary laboratory services for Medicare Part A patients have engaged in a prohibited act under Section 483.245(1), Florida Statutes (2008) and implementing Rule 59A-7.037, Florida Administrative Code. Further, laboratories that engage

in the activities alleged in the Petition may be in violation of Section 400.17, Florida Statutes (2008). In some instances the Agency may be required to show "intent" in order to enforce the applicable law.

2. The Agency specifically makes no declaration regarding federal law including, but not limited to, the Federal Anti-Kickback Statute and opinions interpreting same as cited in Petitioner's Petition for Declaratory Statement.

3. This Declaratory Statement is valid as of the date of issuance. There may be Florida or federal statutes or regulations, and/or decisions in ongoing or future litigation that may change or eliminate the Agency's authority in this matter.

DONE AND ORDERED in Tallahassee, Leon County, Florida, on this 3rd day of July, 2008.


Holly Benson, Secretary
Agency for Health Care Administration

NOTICE


A PARTY WHO IS ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW WHICH SHALL BE INSTITUTED BY FILING ONE COPY OF A NOTICE OF APPEAL WITH THE AGENCY CLERK OF AHCA, AND A SECOND COPY, ALONG WITH FILING FEE AS PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE AGENCY MAINTAINS ITS HEADQUARTERS OR WHERE A PARTY RESIDES. REVIEW OF PROCEEDINGS SHALL BE CONDUCTED IN ACCORDANCE WITH THE FLORIDA APPELLATE RULES. THE NOTICE OF APPEAL MUST BE FILED WITHIN 30 DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

Copies furnished to:

<p>Elizabeth Dudek Deputy Secretary Agency for Health Care Administration 2727 Mahan Drive, Bldg #1, MS #9 Tallahassee, Florida 32308 (Interoffice Mail)</p>	<p>Lester J. Perling, Esq. Vanessa Reynolds, Esq. Broad and Cassel One Financial Plaza, Suite 2700 Fort Lauderdale, Florida 33394 Counsel for Petitioner (U.S. Mail)</p>
<p>Jan Mills Agency for Health Care Administration 2727 Mahan Drive, Bldg #3 MS#3 Tallahassee, Florida 32308 (Interoffice Mail)</p>	<p>Amie C. Ragano, Senior Attorney Office of the General Counsel Agency for Health Care Administration The Sebring Building, Suite 330 525 Mirror Lake Drive North St. Petersburg, Florida 33701 (Interoffice Mail)</p>

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of this Final Order was served on the above-named person(s) and entities by U.S. Mail, or the method designated on this the 7th day of July, 2008.



Richard Shoop, Agency Clerk
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