



MEMORANDUM

RE: **Laboratory Battle Brewing Over Proposed Anti-Kickback Rule Amendment**

DATE: September 15, 2009

Battle lines are being drawn over a proposed rule amendment by the Agency for Health Care Administration (AHCA) with respect to licensure requirements for clinical laboratories. The big issue: whether the state anti-kickback or patient brokering law (Section 483.245(1), Florida Statutes) should prohibit the placement of laboratory staff such as phlebotomists in a physician's office for purpose of collecting lab samples.

In a Declaratory Statement and Final Order entered on July 8, 2008, AHCA had specifically ruled that Florida's clinical lab rules and anti-kickback law prevent the placement of free laboratory personnel in physicians' offices to collect urine samples. The current clinical lab Rule 59A-7.020(15), Florida Administrative Code, provides the following definition of "kickback":

(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:

(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.

Based on this Rule provision, and the underlying anti-kickback statute, AHCA ruled that placing free specimen collection personnel in a physician's office violates the current rule. AHCA also ruled that supplying free specimen collection cups to the physician's offices may also violate anti-kickback prohibitions, if the intent was to induce referral of lab specimens to a

specific laboratory. See In re Declaratory Statement of Dominion Diagnostics, LLC, FRAES No. 100808228 (AHCA July 8, 2008).

After issuing its Declaratory Statement and Final Order, AHCA has been provided with some information that this ruling and interpretation could limit the ability of nursing home residents to access laboratory services, as many of these residents do not have the ability to travel to a laboratory collection site. Many nursing homes rely upon laboratory collection staff provided to the nursing home by a clinical lab for blood or urine sample collection.

Based on concerns over possible limits to access for nursing home residents, AHCA has recently proposed an amendment to its clinical lab rule that defines what is a “kickback.” The proposed rule language includes the following changes to 59A-7.020(15), Florida Administrative Code:

(g) Provision of personnel or assistance of any kind to perform any duties at less than fair market value 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.

The proposed rule change has found little support among operators of clinical laboratories. While most operators clearly oppose the draft rule language, there are two divergent camps emerging: 1) those laboratory operators who believe the practice of supplying free collection personnel to physician offices should continue to be prohibited; 2) those laboratory operators who believe that supplying free collection personnel should not be prohibited, and is entirely consistent with interpretations under Federal anti-kickback laws.

Supporters of a continued ban on allowing free collection personnel to be supplied to physician offices make the following arguments:

- Florida is a progressive state similar to other large states like New York and California in prohibiting laboratories from using free collection staff as an inducement to obtain referrals.
- It is virtually impossible to control what functions the “collection personnel” will provide in a physician’s office, and inevitably they will simply be used as “free labor” to assist with the day-to-day office management of the physician’s practice (e.g. answering phones, making copies, etc.).
- The supplying of free labor is an obvious inducement to make referrals to the lab supplying the collection staff.
- Trying to create a “fair market value” exception is fraught with difficulty, as it is highly debatable whether FMV includes “wages, salaries and benefits” of the worker, or only a “collection fee” for the sample that is drawn.

- In an event, a bright line rule that prohibits the supplying of free labor, even for collection of samples, simplifies enforcement and creates a level playing field for all laboratory operators.
- AHCA visited this issue less than two years ago, and there have been no changes in statute or overall policy that would warrant changing the existing prohibition.
- If AHCA is concerned about access for nursing home patients, then it should carefully craft an exception that applies only to the limited use of specimen collection personnel at by nursing homes.

Opponents of the continued ban on supplying free specimen collection staff argue:

- Florida law should be interpreted consistently with Federal law.
- A 1994 Office of Inspector General (OIG) Fraud Alert specifically finds that supplying free specimen collection personnel such as phlebotomists to a physician office does not necessarily violate federal anti-kickback provisions provided that the staff only engages in activities for specimen collection and not in other clerical or medical functions of the physician's office.
- The Clinical Laboratories Improvement Act (CLIA) as well as Florida regulation of laboratories imposes a duty on laboratories to oversee the proper collection of lab samples.
- Physicians receive no reimbursement for laboratory collection and therefore have no incentive to over-utilize such services, and are receiving no "kick-back" for having qualified collection staff from the laboratory taking samples in the physician office.
- Federal law pre-empts Florida's efforts to regulate, similar to a Florida Supreme Court's finding that federal anti-kickback provisions and safe harbors pre-empted any differing interpretation of Florida Medicaid fraud statutes and regulations. See State v. Harden, 938 So. 2d 480 (Fla. 2006).

After holding a lively Public Workshop on September 14, AHCA announced that it would continue to accept written comments and suggestions on the proposed Rule revision until September 29. There are valid legal and factual arguments to be made on both sides of this debate. Any provider with an interest in laboratory licensure and regulation should take the opportunity to participate in the rule development process.

Future proceedings may include additional workshops. Ultimately, if AHCA elects to proceed with a proposed Rule, any provider that is affected by the Rule has specific rights under Florida's Administrative Procedure Act to file a request for a public hearing and/or a formal challenge to the proposed rule.

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