

**Draft Report
Quality Assurance Committee
Tampa Airport Marriott
Tampa International Airport
Tampa, FL 33607
(813) 879-5151**

July 28, 2006

Members Present:

Raghavendra Vijayanagar, M.D., Chair
Manual Coto, M.D.

Members Absent:

Elisabeth Tucker, M.D.

Staff Present:

Larry McPherson, Jr., J.D., Executive Director
Ed Tellechea, Senior Assistant Attorney General,
Board Counsel
Melinda Gray, Regulatory Supervisor/Consultant

Others Present:

Argus Reporting
Bay Park Reporting
Maryellen O'Brien, Court
Reporter
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Roll Call 11:08 am

Electromyography (Rule 64B17-6.003, F.A.C.) 1

The Board of Medicine previously requested the Board of Physical Therapy to withdraw their Rule 64B17-6.003, F.A.C. which provides the minimum qualifications for physical therapists to perform electromyography. The request was made because s.486.021 (11), F.S. provides that the performance of electromyography by physical therapists can be done only upon compliance with the criteria set forth by the Board of Medicine, not the Board of Physical Therapy. The Board of Physical Therapy declined the request.

Action Taken: The Committee voted unanimously to refer this matter to the Rules Committee to determine whether physical therapist should perform electromyography as stated in the Board of Physical Therapy Rule 64B17-6.003, Florida Administrative Code and for the Board to establish new criteria for physical therapist as stated in s.486.021 (11), Florida Statutes.

Reportable Diseases 2

The Committee reviewed a request from Dr. Saroj Aggarwal, Department of Health, Director of Epidemiology, to make physicians aware that they are required to report diseases of public health significance. The Committee reviewed eight suggestions presented by the Board Office. Of the eight suggestions, the Committee voted unanimously to complete the following:

- Place this information on the web page,
- Place this information on the web board,
- Place this information on our display board at the next full board meeting,
- And contact the Florida Medical Association to provide this information to their members.

Action taken: The Committee voted unanimously to post this information to the web page and web board, include this information on our display board at the next full board meeting, and to provide this information to the Florida Medical Association and Florida Osteopathic Medical Association, and to the Florida Society of Family Practice, Internal Medicine, and Infectious Disease. The Committee also suggested that Dr. Aggarwai write an article for the FMA Journal for physician awareness on reportable diseases.

Questions regarding Advertisements of Ultrasound Technology, Body Scans, and Keepsake Ultrasounds 3

Department Counsel for Unlicensed Activities submitted the following for questions for discussion by the Committee. The Committee addressed each of the below questions.

Advertisement Question #1

An advertisement distributed in Florida states: "A body scan can save your life! Heart disease, stroke, & cancer are the three leading causes of death in America. ... Medical experts agree most heart disease, strokes and cancer can be prevented if detected early. These scans are painless, safe and involve no radiation, no blood testing and no needle injection. During the testing, you will see a picture of your heart, arteries and organs in real-time via color ultrasound." "All tests are administered by certified technologists and evaluated by licensed medical doctors (M.D.)." "You can choose one test or select a package of tests for a reduced price>>>>heart scan, stroke scan, arm & leg scan, deep leg vein scan, aorta artery scan, pancreas scan, gallbladder scan, liver scan, kidney scan, thyroid scan, pelvis scan".

1. Is this the practice of medicine to provide these scans to individuals if the scans or raw data are sent directly with no interpretation of the raw data?

Answer: No

The Committee discussed this matter at length and determined that the "practice of medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition and stated if there is no doctor looking at these scans and not making some type of evaluation or diagnosis, it is not the practice of medicine by its self. However, if these entities send these scans to a physician for interpretation that it is considered the practice of medicine. If a physician becomes involved, and is reading the scan, it is the practice of medicine. Then the physician must comply with Rule 64B8-9.010, which states "64B8-9.010 Interpretation of Diagnostic Imaging Tests or Procedures. Physicians who order, perform, or interpret diagnostic imaging tests or procedures are responsible for the appropriateness and quality of the non-invasive diagnostic procedure, interpretation of the results, diagnosis, and either maintenance of medical records or provision of the results of the test to the referring physician."

2. Is this the practice of medicine to provide these scans to individuals if the scans or raw data are "evaluated" by a licensed medical doctor and the results sent to the individual?

Answer "Yes."

3. Must only a Florida licensed physician evaluate the test results?

Answer: The committee stated that the test results must be evaluated by an appropriately licensed health care practitioner based upon the type of test being evaluated.

Action taken: A motion was made and carried unanimously that question number 1 does not constitute the practice of medicine, questions 2 and 3 clearly constitute the practice of medicine. However, the Committee has concerns about question number 1 because there is no clear prohibition and there seems to be an unsafe practice. The Committee requested that the full Board review question number 1.

Advertisement Question #2

An advertisement is distributed in letter format to Florida residents that states: "Ultrasound technology is used to screen for Peripheral arterial disease and assess your risk of osteoporosis. The good news is that AAA can be identified in minutes via a painless, non-invasive ultrasound screening. A board certified physician licensed in your state evaluates the results and you receive a report within three weeks. As always, you are encouraged to review the results with your own

doctor....the special price package allows you to have the three vascular screening for \$109 and all four screenings for only \$129 – a savings of up to \$41. The three vascular screenings are stroke/carotid artery screening, abdominal aortic aneurysm screening, and peripheral arterial disease screening."

1. Is this the practice of medicine to provide these scans to individuals if the scans or raw data is "evaluated" by a licensed medical doctor and the results sent to the individual?

Answer: Yes

2. If the tests are done for the purpose of detecting named maladies, does the delivery of the test start the doctor-patient relationship?

Answer: Yes

3. Is this an unlicensed practice of medicine issue or a practitioner regulatory issue?

Answer: Regulatory issue.

Action taken: The Committee reviewed and discussed these questions and unanimously answered as indicated above.

Advertisement Question #3

A kiosk in a mall is offering to provide sonograms or ultrasounds to pregnant individuals for the purpose of giving them an "entertainment" picture of their unborn baby.

The Committee discussed whether a company providing sonograms or ultrasounds to pregnant women was considered the practice of medicine and restated that the "practice of medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition. And even though these companies provide sonograms or ultrasound to individuals it is not considered the practice of medicine unless the company is providing health care treatment or referring information to a licensed health care practitioner.

1. Is this the practice of medicine?

Answer: Committee wants review this question to the full Board for review.

2. Is this considered the delivery of medical or health care services?

Answer: Committee wants this question to the full Board for review.

3. Are diagnostic tests, routinely used for medical purposes, considered the delivery of medical or health care services and therefore only to be offered under the request of a health care practitioner licensed in Florida?

Answer: Yes

Questions number 4 and 5 were submitted by a Consumer.

4. Can these ultrasound studies be performed solely for "entertainment and pictures" without any apparent medical indication nor any prescription/referral from a physician or other licensed health care professional (ARNP or Midwife)?

Answer: No

5. Can this business claim to include a limited diagnostic exam of the fetus without being associated or supervised by a licensed physician such as a Diagnostic Radiologist or OB/BYN?

Answer: No, because the business is associated with licensed health care practitioners.

Action taken: The Committee referred questions 1-4 to the full Board for review and consideration.

Questions regarding Medical Assistants and IV Infusions..... 4

Department Counsel for Unlicensed Activities submitted the following for discussion by the Committee:

(1) Section 458.3485, F.S., allows a medical assistant, under direct supervision, to do certain delegable tasks. Many MDs and their attorneys read that statutory section very broadly. I reviewed the staff analysis of the bill and did not see any clear cut intent for that broad-based interpretation. Board Counsel and I agree that the medical assistant can and should do only those functions enumerated in the section. The problem arises when one looks at subsection (a) which states "performing clinical procedures, to *include*: items enumerated in sub sections 1-5. The question is whether or not the M.D. can delegate clinical procedures to a medical assistant under the direct supervision of the physician that may not be particularly stated in 1-5 as long as the physician is willing to take the responsibility **or** is this a narrow list of only those tasks that can be delegated. For example, (c) states that a person can assist with patient treatments....is this intended to be any and all treatments that a MD might be providing??? {Use of lasers, surgical procedures, massage, manipulation, etc.}

The Committee discussed this matter and determined that a medical assistant may perform clinical procedures pursuant to s. 458.3485 (2) (a) 1-5, F.S., and determined that this list is not inclusive. However, the statute does not allow a medical assistant to use lasers, surgical procedures, massage, or manipulation because these are procedures which require a licensure.

Answer: A medical assistant may not perform duties that require health care practitioner licensure.

(2) A medical assistant at a health care clinic licensed under Chapter 400, Part XII, Florida Statutes, was observed and/or admitted to personally performing IV infusions on patients as part of her employment at the clinic. The Agency for Health Care Administration has alleged that this is a violation of s. 400.9935, F.S., which requires, that a health care clinic medical director: (1) ensure that all practitioners providing health care services or supplies to patients maintain a current active and unencumbered Florida license, and (2) ensure that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided.

In addition to the above, in its Administrative Complaint, the Agency alleged that, pursuant to s. 458.3485, F.S., medical assistants are not authorized to perform infusion therapy. The Respondent facility has taken the position that medical assistants are authorized to perform infusion therapy under the direct supervision and responsibility of the physician. The Agency seeks to ascertain DOH's interpretation of s. 458.3485, Florida Statutes.

Answer: A medical assistant cannot perform infusion therapy.

Action taken: A motion was made and carried unanimously to answer questions 1 and 2 as indicated above.

Questions regarding Lasers and Tattoo Removal 5

Department Counsel for Unlicensed Activities submitted the following for questions for discussion by the Committee.

Does the use of a laser or light based device for the removal of a tattoo constitute the unlicensed practice of medicine?

Answer: Yes

Does the use of a laser or light-based device for the treatment of smoking addiction constitute the practice of medicine? The Committee questioned how a laser could be used for treating smoking cessation. The Committee was advised that in the minutes of the Quality Assurance Committee meeting on June 4,

2005, Ms. Henry stated it is the stimulation of acupuncture like points in the ear, nose and hand. It also stimulates energy points that help with weight loss by relaxing the patient and cause the release of endorphins.

Answer: The use of lasers by itself constitutes the practice of medicine and to treat someone for a smoking addiction constitutes the practice of medicine

If the use of a laser or a light-based device for the treatment of smoking addiction constitutes the practice of medicine, which health care professionals are authorized to perform this treatment?

Answer: The use of lasers for treatment of smoking addiction or removal of tattoos constitutes the practice of medicine and an M.D., a Physician Assistant as delegated by the supervising physician and an ARNP under protocol, may use lasers or light-based devices provided the M.D. and the physician extender are qualified by education, training and licensure to do so. Electrologist may only perform laser hair removal under the direct supervision and responsibility of a physician.

Hydrogen Peroxide Infusion Therapy 6

This matter was tabled.

Physician Order for Infusion Therapy Supplemental 7

The Committee received and reviewed the below question from a consumer.

Does one need a physician to specifically order to access a Vascular Access Device when ordering IV fluids?

Answer: Yes. In order to ensure that the individual gets the Vascular Access Device and the IV fluids, the order should state that both should be provided to the individual.

Action taken: A motion was made and carried unanimously to answer the questions as indicated above.

Handout #1: Electronic records affected by 3rd party fee disputes.

This was for information to the Committee. Mr. McPherson explained that he is providing the Committee with a copy of the below story from the South Florida Business Journal from June 30, 2006 to alert them of what may be happening to physicians. There is a Florida based company that, according to news article, is

providing software to physicians to electronically store records and then access records.

The physician signs up for this software and pays a monthly fee, then receives a password for that month. If the physician does not pay the monthly fee then the physician is unable to obtain a password and unable to access the patient records.

According to the article this company has a number of legal actions brought against it. Mr. McPherson wanted to give this information to the Committee as an FYI and to see whether the Committee wanted the Board office to alert practitioners to such practices and that regardless of problems with a 3rd party. The physician is responsible for maintaining patient records.

Action taken: The Committee stated they wanted this matter referred to the full Board.

Handout #2:

The Committee reviewed and discussed the following question concerning e-prescribing submitted from the Executive Director, Board of Pharmacy, dated July 21, 2006:

1. Are the examples below considered signed by the prescribing practitioner when a patient presents a computer generated hard copy of a prescription for filling to the pharmacist that states:

"this has been electronically signed by Dr. Smith";
"this has been approved by Dr. Smith";

Answer: No. This is a paper generated prescription. If it is an electronic signature it must comply with House Bill 1408 and s. 668.003 (4), F.S.

2. Is this example considered signed by the prescribing practitioner when the patient presents a computer generated hard copy prescription that has an electronic version of the physician's actual signature printed on the paper?

Answer: No. If it is a hard copy prescription it must be signed. If it is electronically transmitted it must comply with s. 668.003(4), Florida Statute.

3. Is this example considered signed by the prescribing practitioner when the pharmacy receives a fax (or electronic transmission) of the examples listed in questions #1 and #2 above?

Answer: The e-prescribing must comply with s.668.003 (4), Florida Statutes; otherwise it must comply with the Statute associated with the written prescription Statute

Meeting adjourned at 12:30 pm