

**STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION**

FILED
AHCA
AGENCY CLERK

2016 MAY 10 P 2:00

In Re:)
)
Petition for Declaratory Statement of:) AHCA No. 2016001560
Tallahassee Memorial Healthcare, Inc.)
_____)

DECLARATORY STATEMENT

THIS CAUSE came on for consideration on the petition for declaratory statement (Exhibit A) of the Petitioner, Tallahassee Memorial Healthcare, Inc. (hereinafter “the Petitioner”) filed with the Agency for Health Care Administration (“the Agency”), on February 10, 2016, pursuant to Section 120.565, Florida Statutes (2015), and Rules 28-105.001-.002, Florida Administrative Code. The Petitioner seeks a determination about the applicability of Rule 59A-7.034(7)(a), Florida Administrative Code, as to whether its anesthesiologist assistants licensed under Chapter 458, Florida Statutes, can perform immediate or “STAT” clinical laboratory testing of moderate complexity at alternate sites within Tallahassee Memorial Hospital under the direct supervision of an anesthesiologist licensed under Chapter 458 or 459, Florida Statutes. Notice of the petition for declaratory statement was published in the Florida Administrative Register at Volume 42, Number 37, on February 24, 2016.

JURISDICTION

1. The Petitioner is licensed by the Agency to operate a clinical laboratory pursuant to Chapters 408, Part II, and 483, Part I, Florida Statutes (2015). A license issued by the Agency is required to operate a clinical laboratory in Florida. § 483.23, Fla. Stat. (2015).

2. The Agency is the state agency that licenses and regulates clinical laboratories in Florida under the Health Care Licensing Procedures Act, Chapter 408, Part II, Florida Statutes,

the authorizing statutes, Chapter 483, Part I, Florida Statutes, and the administrative rules, Chapter 59A-7, Florida Administrative Code. The Agency has substantive jurisdiction over the statutes in question.

QUESTION PRESENTED

3. The Petitioner seeks a determination as to whether its anesthesiologist assistants can perform immediate or “STAT” clinical laboratory testing of moderate complexity at alternate sites within its hospital under the direct supervision of an anesthesiologist licensed under Chapter 458 or 459, Florida Statutes.

THE STATEMENT OF FACTS

4. The Petition makes the following allegations, which the Agency relies upon without taking any position on the validity of the facts. See Fla. Admin. Code R. 28-105.003.

a. The Petitioner owns and operates Tallahassee Memorial Hospital, a 772-bed full-service acute care hospital licensed under Chapter 395, Florida Statutes.

b. The Petitioner operates a clinical laboratory at the hospital which is duly licensed under Chapter 483, Florida Statutes.

c. The Petitioner performs testing at alternate sites within the hospital.

d. The Petitioner’s clinical laboratory at TMH is licensed in all of the specialties and subspecialties in which alternate-site testing is performed.

e. The alternate-site testing is performed through authorized personnel in accordance with Rule 59A-7.034, Florida Administrative Code.

f. The Petitioner desires to perform alternate-site testing of moderate complexity through anesthesiologist assistants licensed under Chapter 458, Florida Statutes.

g. Such testing would consist exclusively of immediate or “STAT” laboratory

testing on surgical patients under anesthesia.

5. In addition, the Petition set out the following scenario.

TMH performs testing at alternate sites within the Hospital through authorized personnel in accordance with Rule 59A-7.034, Florida Administrative Code. The TMH clinical laboratory is licensed in all of the specialties and subspecialties in which alternate-site testing is performed. TMH desires to perform alternate-site testing of moderate complexity through anesthesiologist assistants licensed under Chapter 458, Florida Statutes. Such testing would consist exclusively of immediate or “STAT” laboratory testing on surgical patients under anesthesia. STAT laboratory testing on surgical patients consists primarily of tests for blood chemistry (e.g. potassium and glucose levels), blood gas (e.g. oxygen saturation), and blood clotting time. STAT laboratory testing is performed in the operating room in a matter of minutes while the patient is under anesthesia. It is vitally important to the treatment of surgical patients under anesthesia. Regardless of how routine a procedure may be, the condition of a patient under anesthesia can become critical in a matter of minutes, and the anesthesiologist needs immediate access to STAT laboratory results to manage conditions such as hemorrhaging, hypoxia, and metabolic imbalance. Often, though, the anesthesiologist cannot perform STAT laboratory testing because he or she is providing anesthesia care to the patient or another patient at the same facility. This requires other personnel assisting the anesthesiologist to perform the testing. Anesthesiologist assistants - who are already in the room and are directly involved in the patient’s care - are in the best position to conduct STAT laboratory testing for the anesthesiologist.

THE AGENCY STATUTES AND RULE

6. Section 483.051, Florida Statutes (2015), provides in part:

Powers and duties of the agency.—The agency shall adopt rules to implement this part, which rules must include, but are not limited to, the following:

(9) ALTERNATE-SITE TESTING.— The agency, in consultation with the Board of Clinical Laboratory Personnel, shall adopt, by rule, the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director. The elements to be addressed in the rule include, but are not limited to: a hospital internal needs assessment; a protocol of implementation including tests to be performed and who will perform the tests; criteria to be used in selecting the method of testing to be used for alternate-site testing; minimum training and education requirements for those who will perform alternate-site testing, such as documented training, licensure, certification, or other medical professional background not limited to laboratory professionals; documented inservice training as well as initial and ongoing competency validation; an appropriate internal and external quality control protocol; an internal mechanism for identifying and tracking alternate-site testing by the central laboratory; and recordkeeping

requirements. Alternate-site testing locations must register when the clinical laboratory applies to renew its license. For purposes of this subsection, the term “alternate-site testing” means any laboratory testing done under the administrative control of a hospital, but performed out of the physical or administrative confines of the central laboratory.

7. Section 483.813, Florida Statutes (2015), provides in part:

Clinical laboratory personnel license. — A person may not conduct a clinical laboratory examination or report the results of such examination unless such person is licensed under this part to perform such procedures. However, this provision does not apply to any practitioner of the healing arts authorized to practice in this state or to persons engaged in testing performed by laboratories regulated under s. 483.051(1) or exempt from regulation under s. 483.031(2). The department may grant a temporary license to any candidate it deems properly qualified, for a period not to exceed 1 year.

8. Section 483.803(7), Florida Statutes (2015), provides:

(7) “Licensed practitioner of the healing arts” means a physician licensed under chapter 458, chapter 459, chapter 460, or chapter 461; a dentist licensed under chapter 466; or a person licensed under chapter 462.

9. Section 483.801, Florida Statutes (2015), states in part:

Exemptions.—This part applies to all clinical laboratories and clinical laboratory personnel within this state, except:

- (1) Clinical laboratories operated by the United States Government.
- (2) Laboratories operated and maintained exclusively for research and teaching purposes, involving no patient or public health service whatsoever.
- (3) Persons engaged in testing performed by laboratories regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2).
- (4) Respiratory therapists and respiratory care practitioners certified or registered under part V of chapter 468.
- (5) Advanced registered nurse practitioners licensed under part I of chapter 464 who perform provider-performed microscopy procedures (PPMP) in an exclusive-use laboratory setting.

10. The Legislature has granted the Agency, in consultation with the Board of Clinical Laboratory Personnel, authority to adopt rules related to the “minimum training and education requirements for those who will perform alternate-site testing, such as documented training, licensure, certification, or other medical professional background not limited to

laboratory professionals.” § 483.051, Fla. Stat. (2015). Pursuant to this statute, Rule 59A-7.034, Florida Administrative Code, was promulgated.

11. Rule 59A-7.034, Florida Administrative Code, states in part:

(7) Alternate-Site Testing Personnel Requirements: Staff performing the testing at these alternate-sites, as authorized under this subsection, are not required to be licensed under Chapter 483, Part III, F.S., as clinical laboratory personnel.

(a) Testing personnel shall have a high school diploma, or its equivalent, and have met the HIV/AIDS educational requirements pursuant to Section 381.0035, F.S. In addition, all testing personnel in the alternate-test site locations shall meet one of the following requirements:

1. Is licensed as an advanced registered nurse practitioner, a registered nurse or licensed practical nurse pursuant to Chapter 464, F.S.;
2. Is licensed as a radiologic technologist pursuant to Chapter 468, Part IV, F.S.;
3. Is licensed as a respiratory care practitioner certified in critical care services or a respiratory therapist pursuant to Chapter 468, Part V, F.S.
4. Is a phlebotomist certified by the American Society of Clinical Pathologists (ASCP), National Certification Agency for Medical Laboratory Personnel (NCA), American Society of Phlebotomy Technicians (ASPT) or American Medical Technologists (AMT);
5. Is licensed as a physician assistant pursuant to Chapters 458 and 459, F.S.;
6. Is a perfusionist certified by the American Board of Cardiovascular Perfusion, determined eligible for certification by the American Board of Cardiovascular Perfusion, or has two years of clinical experience in cardiovascular perfusion with 100 clinical perfusions conducted as of January 1, 1981;
7. Is a cardiovascular technician certified by the Cardiovascular Credentialing International (CCI);
8. Is licensed as a director, supervisor, technologist or technician under Chapter 483, Part III, F.S., or exempt from such licensure as provided in that chapter;
9. Is a licensed Emergency Medical Technician (EMT) or Paramedic pursuant to Chapter 401, F.S., or
10. Meets the staff training and education requirements set out in the alternate-site policy and procedure manual developed by the laboratory director for individuals performing tests categorized as waived. Individuals who meet such staff training and education requirements for performing tests categorized as waived, but who do not meet the requirements for performing moderate complexity tests as provided under this rule, are restricted to performing tests categorized as waived.

DISCUSSION

12. “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. (2015). “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.

8. “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-Mutuel Wagering v. Investment Corporation of Palm Beach, 747 So.2d 374, 382 (Fla. 1999).

9. The determination of the Petition begins with section 483.813, Florida Statutes (2015), which states: “A person may not conduct a clinical laboratory examination or report the results of such examination unless such person is licensed under this part to perform such procedures.” § 483.813, Fla. Stat. (2015). Permitted practitioners under this provision include

staff which: “Is licensed as a director, supervisor, technologist, or technician under Chapter 483, Part III, F.S., or exempt from such licensure as provided in that chapter.” R. 59A-7.034(7)(a)8., Fla. Admin. Code. Anesthesiologist assistants are not licensed or exempt under Chapter 483, Part III, Florida Statutes, and therefore may not perform alternate-site clinical laboratory testing under this part of the statute.

10. Section 483.813, Florida Statutes, also provides that the provision “does not apply to any practitioner of the healing arts authorized to practice in this state....” Under 483.083, Florida Statutes (2015): “Licensed practitioner of the healing arts” means a physician licensed under chapter 458, chapter 459, chapter 460, or chapter 461; a dentist licensed under chapter 466; or a person licensed under chapter 462.”¹ Anesthesiologist assistants do not fall under the definition of “licensed practitioner of the health arts” and are not otherwise identified in Section 483.813, Florida Statutes, or Rule 59A-7.034(7) as personnel who may perform alternate-site clinical laboratory testing. Accordingly, anesthesiologist assistants are not legally qualified to perform such testing under current law.

11. The Petitioner maintains that because anesthesiologist assistants must work under the direct supervision of anesthesiologists who are liable for their performance, anesthesiologist assistants are essentially extensions of anesthesiologists. The Petitioner posits that any testing performed by an anesthesiologist assistant constitutes testing performed by an anesthesiologist for purposes of Rule 59A-7.034(7), and thus the statutory provisions qualifying anesthesiologists to perform alternate-site testing should extend to anesthesiologist assistants. *Petition page 2-3.*

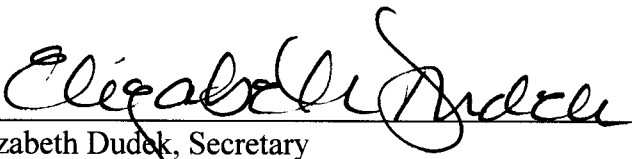
¹ In addition, anesthesiologist assistants are not included in the definition “licensed practitioner” under subsection 483.041(7), Florida Statutes (2015) (“Licensed practitioner” means a physician licensed under chapter 458, chapter 459, chapter 460, or chapter 461; a certified optometrist licensed under chapter 463; a dentist licensed under chapter 466; a person licensed under chapter 462; a consultant pharmacist or doctor of pharmacy licensed under chapter 465; or an advanced registered nurse practitioner licensed under part I of chapter 464; or a duly licensed practitioner from another state licensed under similar statutes who orders examinations on materials or specimens for nonresidents of the State of Florida, but who reside in the same state as the requesting licensed practitioner.”).

12. The Petitioner's argument is not supported by a plain reading of the statutes and rule. The Agency declines to opine on the permissible scope of services and the differing roles between anesthesiologists and anesthesiologist assistants since that determination lies within the province of the Legislature and the Florida Department of Health.

DECLARATION

13. The Agency declares that under the current law, anesthesiologist assistants are not permitted to perform clinical laboratory testing of moderate complexity at alternate sites within a hospital unless they are licensed as clinical laboratory personnel under Chapter 483 Part III, Florida Statutes (2015).

ORDERED in Tallahassee, Florida, on this 10 day of May, 2016.

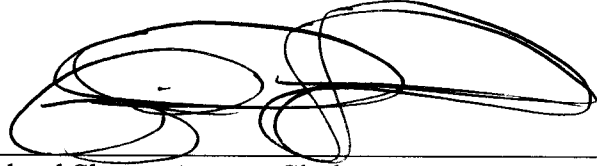

Elizabeth Dudek, Secretary
Agency for Health Care Administration

NOTICE OF RIGHT OF JUDICIAL REVIEW

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.

CERTIFICATE OF SERVICE

I **CERTIFY** that a true and correct copy of this Final Order was served on the below-named persons by the method designated on this 10th day of May, 2016.



Richard Shoop, Agency Clerk
 Agency for Health Care Administration
 2727 Mahan Drive, MS #3
 Tallahassee, Florida 32308-5403
 (850) 412-3630

Jan Mills, Government Analyst Facilities Intake Unit Agency for Health Care Administration (Electronic Mail)	Dayle Mooney, Acting Unit Manager Laboratory Unit Agency for Health Care Administration (Electronic Mail)
Kevin M. Marker, Assistant General Counsel Office of the General Counsel Agency for Health Care Administration (Electronic Mail)	Jack Plagge, Unit Manager Hospital and Outpatient Services Unit Agency for Health Care Administration (Electronic Mail)
Joint Administrative Procedures Committee Room 680, Pepper Building 111 West Madison Street Tallahassee, Florida 32399 (U.S. Mail)	D. Carlton Enfinger, Senior Attorney Office of the General Counsel Agency for Health Care Administration (Electronic Mail)
Brian A. Newman, Esquire Gerald D. Bryant, Esquire Pennington, P.A. 215 South Monroe Street, Suite 200 Tallahassee, Florida 32301 (U.S. Mail)	

PETITION FOR DECLARATORY STATEMENT
BEFORE THE AGENCY FOR HEALTH CARE ADMINISTRATION

Petitioner, TALLAHASSEE MEMORIAL HEALTHCARE, INC. ("TMH"), by and through the undersigned counsel, files this Petition for Declaratory Statement pursuant to Section 120.565, Florida Statutes, and Rule 28-105.002, Florida Administrative Code, and requests a declaratory statement regarding the ability of anesthesiologist assistants licensed under Chapter 458, Florida Statutes, to perform immediate or "STAT" clinical laboratory testing of moderate complexity at alternate sites within Tallahassee Memorial Hospital under the direct supervision of an anesthesiologist licensed under Chapter 458 or Chapter 459, Florida Statutes.

THE PETITIONER

1. The Petitioner, TMH, is a not-for-profit corporation organized under the laws of the State of Florida. TMH's address is 1300 Miccosukee Road, Tallahassee, Florida, 32308. TMH's email address, phone number, and facsimile number are that of its counsel for purposes of this Petition.

2. TMH is represented in this matter by the undersigned counsel, Brian A. Newman and Gerald D. Bryant of Pennington, P.A., whose address is 215 S. Monroe Street, Suite 200, Tallahassee, Florida, 32301. Counsel may be contacted by phone at (850) 222-3533, email at brian@penningtonlaw.com and jbryant@penningtonlaw.com, or facsimile at (850) 222-2126.

THE RULE

3. TMH is seeking a declaratory statement regarding Rule 59A-7.034(7)(a), Florida Administrative Code (the "Rule"), which implements section 483.051(9), Florida Statutes. The Rule identifies multiple categories of personnel who, provided they meet certain other education and training requirements, may perform alternate-site clinical laboratory testing of moderate complexity. One of those categories is:

EXHIBIT A

viii. Licensed directors, supervisors, technologists, or technicians under Chapter 483, Part III, F.S., or those exempt from such licensure as provided in that chapter. (Emphasis supplied.)

4. Anesthesiologists fall within this category because they are exempt from licensure under Chapter 483, Part III. See § 483.813, Fla. Stat. Thus, anesthesiologists are clearly authorized to perform alternate-site clinical laboratory testing of moderate complexity.

5. TMH believes that anesthesiologist assistants working under the direct supervision of an anesthesiologist also fall within this category for the following reasons.

6. Pursuant to section 458.3475, Florida Statutes, anesthesiologist assistants must work under the direct supervision of an anesthesiologist when providing anesthesia services. Direct supervision is “onsite, personal supervision by an anesthesiologist who is present in the office when the procedure is being performed in that office, or is present in the surgical or obstetrical suite when the procedure is being performed in that surgical or obstetrical suite and who is in all instances immediately available to provide assistance and direction to the anesthesiologist assistant while anesthesia services are being performed.” § 458.3475(1)(g), Fla. Stat. Thus, whenever an anesthesiologist assistant provides anesthesia services, he or she must do so under the onsite, personal supervision of an anesthesiologist who is responsible *and liable for* all services provided by the anesthesiologist assistant. § 458.3475(2)(a), Fla. Stat. (stating that “anesthesiologist who directly supervises an anesthesiologist assistant... is liable for the performance of the anesthesiologist assistant”). This is why anesthesiologist assistants are often referred to as physician “extenders” – they serve as extensions of the physicians themselves.

7. Because anesthesiologist assistants must work under the direct supervision of an anesthesiologist, the anesthesiologist would always supervise and be liable for any clinical

laboratory testing performed by the anesthesiologist assistant. Thus, testing performed by an anesthesiologist assistant constitutes testing performed by the anesthesiologist for purposes of Rule 59A-7.034(7)(a).

HOW THE RULE MAY SUBSTANTIALLY AFFECT TMH

8. TMH owns and operates Tallahassee Memorial Hospital (the "Hospital"), a 772-bed full-service acute care hospital licensed under Chapter 395, Florida Statutes. TMH operates a clinical laboratory at the Hospital which is licensed under Chapter 483, Florida Statutes.

9. TMH performs testing at alternate sites within the Hospital through authorized personnel in accordance with Rule 59A-7.034, Florida Administrative Code. The TMH clinical laboratory is licensed in all of the specialties and subspecialties in which alternate-site testing is performed.

10. TMH desires to perform alternate-site testing of moderate complexity through anesthesiologist assistants licensed under Chapter 458, Florida Statutes. Such testing would consist exclusively of immediate or "STAT" laboratory testing on surgical patients under anesthesia.

11. STAT laboratory testing on surgical patients consists primarily of tests for blood chemistry (e.g. potassium and glucose levels), blood gas (e.g. oxygen saturation), and blood clotting time. STAT laboratory testing is performed in the operating room in a matter of minutes while the patient is under anesthesia. It is vitally important to the treatment of surgical patients under anesthesia. Regardless of how routine a procedure may be, the condition of a patient under anesthesia can become critical in a matter of minutes, and the anesthesiologist needs immediate access to STAT laboratory results to manage conditions such as hemorrhaging, hypoxia, and metabolic imbalance. Often, though, the anesthesiologist cannot perform STAT

laboratory testing because he or she is providing anesthesia care to the patient or another patient at the same facility. This requires other personnel assisting the anesthesiologist to perform the testing. Anesthesiologist assistants – who are already in the room and are directly involved in the patient’s care – are in the best position to conduct STAT laboratory testing for the anesthesiologist.

WHEREFORE, Petitioner, Tallahassee Memorial Healthcare, Inc., respectfully requests that the State of Florida, Agency for Health Care Administration, issue a declaratory statement stating that anesthesiologist assistants may perform immediate or “STAT” clinical laboratory testing of moderate complexity at alternate sites within Tallahassee Memorial Hospital under the direct supervision of anesthesiologists licensed under Chapter 458 or Chapter 459, Florida Statutes.

Respectfully submitted this 10th day of February, 2016.



Brian A. Newman
Florida Bar No: 04758
Gerald D.N. Bryant, IV
Florida Bar No. 58288
PENNINGTON, P.A.
215 S. Monroe Street, Suite 200
Tallahassee, Florida 32301
Telephone: (850) 222-3533
Facsimile: (850) 222-2126
Attorneys for Petitioner