



MEMORANDUM

RE: Alternate-Site Testing in Hospitals

DATE: May 24, 2010

The Agency for Health Care Administration (AHCA) will be holding a public meeting on Tuesday, May 25, 2010, at its Tallahassee headquarters to discuss current practices and requirements under the “Alternate-Site Testing” rule (Rule 59A-7.034, Florida Administrative Code). Simply stated, the alternate-site testing rule allows for certain laboratory tests to be performed by designated hospital personnel at sites other than the hospital’s licensed clinical laboratory. Examples of alternate sites are the patient’s bedside, emergency room, or nurses’ station. Hospitals must have approval from AHCA to conduct alternate-site tests.

Navigating through Rule 59A-7.034 can be a daunting task for a hospital seeking approval for alternate-site testing. At this time, there is no standard application form to submit for approval to test at alternate sites. Therefore, careful attention to each requirement in the rule is necessary to ensure that the hospital’s alternate-site testing is approved. This article will provide a brief overview of the rule’s requirements.

History of Alternate-Site Testing

The alternate-site statute was signed into law in 1993. Section 483.051(9), Florida Statutes, required AHCA, DOH and the Board of Clinical Laboratory Personnel to adopt criteria for alternate-site testing performed under the supervision of a clinical laboratory director. In 1995, Rule 59A-7.034, Florida Administrative Code, was adopted. The rule was amended in 2009 to further specify the parameters for tests performed at alternate test sites within hospitals.

Overview of Laboratory Testing at Alternate Sites

Generally, clinical laboratory testing may be done at a hospital’s main or central laboratory or satellite laboratories, which are licensed clinical laboratories established on the

MEMORANDUM

May 24, 2010

same or adjoining grounds of a hospital licensed under Chapter 395. Testing at satellite labs must be done by licensed clinical laboratory personnel. However, the Legislature created a limited exception to this requirement under Section 483.051(9), Florida Statutes, which allows for alternate-site testing. 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. Section 483.051(9), Florida Statutes.

Alternate-site testing provides two distinct advantages for hospitals with a licensed clinical laboratory on site. First, certain lab tests can be performed bedside, at a nurse station, operating room, ER or anywhere else under the administrative control of a hospital. Second, alternate-site testing can be performed by non-clinical laboratory personnel if agency approval is granted under Rule 59A-7.034.

If hospital staff (other than licensed clinical laboratory personnel) will be performing the tests at alternate sites, then an *internal needs assessment* must be submitted for agency approval of alternate-site testing. The assessment must be completed by the laboratory director and contain specific information relating to the patient benefits and criteria for testing, proposed methodologies for tests, and other information and protocols to insure the accuracy and integrity of the tests being performed at the alternate site. The internal needs assessment – along with a list of the clinical tests and testing locations where they are to be performed – must be submitted with each biennial laboratory licensure renewal application.

Who can perform tests at alternate sites?

Licensed clinical laboratory personnel can always perform certain tests at alternate sites as long as the laboratory director is responsible for the testing. If a laboratory clinician is not performing the test, there are specific personnel requirements for the tester. Testers must have a high school diploma, have met the HIV/AIDS educational requirements, and be one of the following (with designated certifications or exemptions): RN, LPN, radiologic technologist, respiratory care practitioner certified in critical care services, respiratory therapist, nationally-certified phlebotomist, physician's assistant, perfusionist, cardiovascular technician, or any licensed director, supervisor technologist or technician under Chapter 483. The laboratory director is responsible for training, evaluating for competency and documenting necessary qualifications of all personnel to perform alternate-site testing.

What tests can be performed under alternate-site rule?

Any test the supervising director and laboratory personnel are qualified to conduct can be documented in the internal needs assessment for approval from AHCA. However, certain restrictions apply. In general, the tests performed at alternate sites must not exceed "moderately complex" test procedures. Further, they must employ whole blood specimens that require no

MEMORANDUM

May 24, 2010

processing of any kind and use automated test systems in which a specimen is directly introduced into the system.

Where can alternate-site tests be conducted?

Alternate-site testing can only be conducted at those sites where the laboratory director has established and documented as necessary for the proper care and treatment of patients in the internal needs assessment. Each test site must have a procedure manual that specifically addresses the testing done at that location and shall be noted on all laboratory licensure applications submitted to the agency.

Violations

AHCA may revoke the approval for any alternate-testing site where the agency determines that said sites have operated in violation of Chapter 483, Part 1, of the Florida Statutes, or the provisions of Rule 59A-7. Further, it may even revoke the license of the laboratory maintaining the alternate-site testing in the event of a violation.

Conclusion

Hospital laboratories must assess what tests will be performed at alternate sites and who will be performing them before applying to AHCA for alternate-site testing approval. Because AHCA has not yet developed a standardized application for alternate-site approval, hospitals must create a letter-form application that carefully addresses each requirement under Rule 59A-7.034.

If you need assistance with obtaining approval for alternate-site testing, please feel free to call us.