APA-1
6/93

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Department or Agency Alabama Department of Public Health

Rule Number 420-5-8
Rule Title Independent Clinical Laboratories and Independent Physiological Laboratories

_____ New XXX Amend _____ Repeal _____ Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety?	Yes
Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare?	Yes
Is there another, less restrictive method of regulation available that could adequately protect the public?	No
Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree?	No
Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule?	NA
Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public?	Yes
Does the proposed rule have an economic impact?	No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of Certifying Officer Patricia Shue Date 4/16/14

FORM APA2
11/96

STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-5-8 Independent Clinical Laboratories and Independent Physiological Laboratories

INTENDED ACTION: To amend the current rules

SUBSTANCE OF PROPOSED ACTION: To revise the current rules to eliminate the requirement for proficiency testing for CLIA waived tests approved by the United States Food and Drug Administration, consistent with current federal regulations.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held on May 14, 2014, at 9:00 a.m., in the Office of General Counsel, Suite 1540, the RSA Tower, 201 Monroe Street, Montgomery, AL 36104. Written comments should be mailed to the agency contact person noted below.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on June 4, 2014. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Walter T. Geary Jr., M.D., Director, Bureau of Health Provider Standards, Department of Public Health, P.O. Box 303017, Montgomery, Alabama 36130-3017, Telephone number: (334) 206-5366.

Patricia E. Ivie, Agency Secretary

420-5-8-.04 Management.

(1) Personnel.

(a) The laboratory shall be under the direction of a director and shall provide the number of other qualified personnel commensurate with the volume and type of tests performed.

(b) The laboratory shall perform only those laboratory procedures and tests that are within the specialties or subspecialties in which the laboratory director, supervisors, or persons engaged to perform tests are qualified.

(c) The laboratory may perform laboratory procedures and tests in all specialties provided that the director or supervisor is a pathologist certified or eligible for certification in both anatomical and clinical pathology by the American Board of Pathology or American Osteopathic Board of Pathology.

(d) In circumstances where AAC Rule 420-5-8.04(1)(c) is not met, the following criteria shall be used to establish qualifications of laboratory personnel to perform each specialty:

1. Microbiology, including serology - The laboratory engages the services of an individual who holds an earned doctoral degree or master's degree in microbiology from an accredited institution or is a licensed practitioner of the healing arts with two years of experience in microbiology.

2. Hematology - The laboratory engages the services of an individual who holds a master's or bachelor's degree in biology, immunology or microbiology from an accredited institution and has had at least four years experience in hematology or is a licensed practitioner of the healing arts with pertinent experience.

3. Immunohematology - The laboratory engages the services of a licensed physician with specific experience in this field or an individual with a master's or bachelor's degree in biology, immunology or microbiology from an accredited institution and has four years of experience in immunohematology.

4. Chemistry - The laboratory engages the services of an individual who holds an earned doctoral degree or master's degree in chemistry or biochemistry from an accredited institution or is a licensed practitioner of the healing arts with two years experience in clinical chemistry.

5. Histopathology - The laboratory engages the services of a licensed practitioner in the healing arts who is certified in anatomic pathology or is eligible for certification

by the American Board of Pathology or the American Board of Osteopathic Pathology or possesses qualifications which are equivalent to those required for certification by these Boards.

6. Cytotechnology - The laboratory engages the services of a licensed practitioner of the healing arts who is certified in anatomic pathology or is eligible for certification by the American Board of Pathology or the American Osteopathic Board of Pathology or is certified by the American Society of Cytology to practice cytopathology or who possesses qualifications which are equivalent to those required for certification by these Boards.

(2) Operation.

(a) Equipment shall be provided and maintained for the proper performance of the specialties and volume of service offered.

(b) The laboratory shall be in compliance with all state and local laws and regulations including those relating to construction and sanitary conditions and also including the handling and disposal of specimens.

(3) Administration and Organization.

(a) The director shall serve the laboratory full time or on a regular part-time basis and shall be readily available for personal or telephone consultations.

(b) If the director is not in attendance throughout normal periods of operation, at least one clinical laboratory supervisor shall be available and on the premises.

(c) The licensee shall be responsible for the proper maintenance and conduct of the laboratory.

(4) Procedures and Equipment.

(a) All technical procedures employed in the laboratory shall be the standard procedures which are generally accepted by leading authorities in microbiology, serology, chemistry, hematology, immunohematology, biophysics, cytotechnology, and histopathology as applicable or are equivalents approved by the Alabama Department of Public Health.

(b) There shall be quality control procedures in effect, including the use of reference and control sera and other biological samples, calibrating standards, and control charts.

(c) All equipment shall be in good working order, routinely checked and calibrated, and documentation of checks and calibrations shall be maintained.

(d) Syringes, needles, lancets, or other blood-letting devices capable of transmitting infection from one person to another shall be cleaned and sterilized prior to each use. Each sterilizing cycle shall contain an indicator device which assures proper sterilization.

(e) A specimen received by a laboratory shall not be tested or reported if:

1. The apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested.

2. It has been collected, labeled, preserved, or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen.

3. It is perishable and the time lapse between the collection of the specimen and its receipt by the laboratory is of such duration that the test finding may no longer be reliable.

4. When a specimen is not tested for any of the reasons specified in AAC Rule 420-5-8.04(4)(e), the laboratory shall promptly notify the sender and give the reason therefore.

(f) Notebooks or manuals containing appropriate current laboratory methods shall be maintained.

(5) Records and Reports.

(a) All changes in clinical laboratory personnel shall be reported to the Alabama Department of Public Health initially and annually at time of licensing.

(b) Modifications of facilities or services affecting the operation of the laboratory shall be reported to the Alabama Department of Public Health annually at the time of licensing.

(c) The laboratory shall participate in one or more of the proficiency testing programs offered by state or private organizations approved by the Alabama Department of Public Health. The results of such programs shall be made available to the Alabama Department of Public Health for review upon request. Proficiency testing is not required for CLIA waived tests as published by the U.S. Food and Drug Administration at http://www.fda.gov.

(d) Records shall be maintained on each specimen received for testing and shall contain the following information:

1. Laboratory number or other identification of the specimen.

2. Name and other identification of the person from whom the specimen was taken.

3. Name and address of the licensed practitioner of the healing arts or other authorized person or clinical laboratory that submitted the specimen.

4. Date the specimen was collected.

5. Condition of unsatisfactory specimens when received (e.g., broken, leaked, hemolyzed, turbid).

6. Date the specimen was received.

7. Date the specimen was tested.

8. Type of test performed.

9. Complete information as to the disposition of the specimen when it has been referred to another laboratory for examination.

10. Result of test and date of reporting.

(e) The laboratory director is responsible for laboratory reports and the following records shall be maintained:

1. Tissue pathology reports utilizing acceptable terminology of a recognized system of disease nomenclature.

2. Duplicate copies of laboratory reports shall be filed in the laboratory or stored in a readily accessible location for at least two years.

3. Records and reports of examinations of all specimens shall be treated as confidential information.

(6) Collection Stations.

(a) Clinical laboratories operating collection stations within this state shall obtain a license from the Alabama Department of Public Health for each collection station. Such collection stations shall be maintained in accordance with the following requirements:

1. A refrigerator which maintains a temperature of 40-50 degrees F. shall be available on the premises for storage of specimens.

2. Syringes, needles, lancets, or other blood-letting devices capable of transmitting infection from one person to another shall be clean and sterile prior to use. Each sterilizing cycle shall contain an indicator device which assures proper sterilization.

3. Laboratory tests shall not be performed at collection stations.

4. Records shall be maintained indicating the daily accession of specimens containing the following information:

(i) Name and other identification of the person from whom specimen was obtained.

(ii) Name and address of the licensed practitioner of the healing arts or other authorized person or clinical laboratory who submitted the specimen.

(iii) Date the specimen was collected.

(iv) Date the specimen was received.

(v) Type of test requested.

(vi) Name and address of referring laboratory or authorized person.

(b) Procedure manuals relating to the procedures performed by the collection station shall be maintained in laboratories and collection stations.

(7) Plasmapheresis and Whole Blood Donor Centers.

(a) Methods shall be provided for the selection of donors and for the collection, storage, processing and transfusion, which shall ensure as far as possible that: 1) the donation is not detrimental to the donor, and, 2) the recipient of the donated human blood or any of its components is protected from exposure to infectious diseases known to be transmissible by blood.

(b) Written policies and procedures shall conform to the current edition of the American Association of Blood Banks' Standards for Blood Banks and Transfusion Services. Copies of this reference may be purchased from: American Association of Blood Banks, 1117 North 19th Street, Suite 600, Arlington, Virginia 22209, telephone number 1-703-528-8200, or may be inspected at the office of the Alabama Department of Public Health, Division of Licensure and Certification, Laboratory Section, Montgomery, Alabama.

(c) Personnel Requirements.

1. Director shall meet at least the requirements specified in AAC Rule 420-5-8.03(1)(a)(1) and shall be responsible at all times for all phases of operation.

2. Donor Selection (Screening Area)..

(i) This area shall be staffed with at least one person with no lesser qualifications than that of a Licensed Practical Nurse (LPN), Clinical Laboratory Technician (MLT), or equivalent level of training or experience (approved by the Alabama Department of Public Health). Said qualified person shall be assigned the responsibility for supervision of all activities of the donor screening area (including such laboratory procedures as total serum protein, urine dipstick tests, hemoglobin and hematocrit testing).

(ii) Every person employed in the screening area shall receive ongoing continuing or in-service education to enable him to recognize abnormalities that could make it detrimental to the donor to donate (i.e., problem with blood pressure, pulse, etc.) and to conduct careful evaluations of donor suitability in accordance with the outline for donor selection published by the American Association of Blood Banks. Documentation of the continuing or in-service education for each donor screening employee shall be available for review by the Alabama Department of Public Health.

3. Phlebotomy Area.

(i) Phlebotomists shall be persons who have a minimum of one month's training in a plasmapheresis or blood donor center.

(ii) A phlebotomist shall be employed for the care of each four (or fraction of four) donors being processed at one time.

(iii) The phlebotomy area shall be supervised by a person with no lesser qualifications than that of a Licensed Practical Nurse (LPN), Clinical Laboratory Technician (MLT), or equivalent level of training and/or experience (approved by the Alabama Department of Public Health). Said supervisor shall be certified in cardiopulmonary resuscitation (CPR) annually. It is permissible for one qualified person to supervise both the donor screening area and the phlebotomy area.

4. Plasmapheresis or Whole Blood Donor Testing Centers. Plasmapheresis or Whole Blood Donor Centers that perform any laboratory procedures other than screening procedures such as total serum protein, urine dipstick, hemoglobin and hematocrit testing, must comply with all provisions of the Alabama Administrative Code (AAC), Chapter 420-5-8, Rules of the Alabama State Board of Health for Independent Clinical Laboratories and Independent Physiological Laboratories.

5. Other Personnel. Aides, clerks, volunteer workers, etc., may be employed in the center but shall not perform technical duties.

(d) Proficiency Testing Requirements. The center shall participate in one or more of the proficiency testing programs approved by the Alabama Department of Public Health. The results of such programs shall be made available to the Alabama Department of Public Health for review.

(e) Quality Control Requirements. Quality control requirements shall be in accordance with AAC 420-5-8.04(4)(b).

(f) Documentation of Reactions.

1. The facility shall maintain a records system documenting all reactions.

2. Adequate reporting and recording forms shall be available and utilized.

Authors: L. O'Neal Green, Patricia E. Ivie, Rick Harris
Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed September 1, 1982. **Amended:** filed November 20, 1992. **Amended:** Filed May 20, 1996; effective June 24, 1996. **Amended:** Filed December 20, 2002;; effective January 24, 2003.