ALABAMA SICKLE CELL OVERSIGHT AND REGULATORY COMMISSION ADMINISTRATIVE CODE

CHAPTER 825-X-2
CRITERIA FOR COMPREHENSIVE SICKLE CELL CENTERS AND SICKLE CELL CHAPTERS RECEIVING STATE SUPPORT THROUGH THE EDUCATION TRUST FUND OR THROUGH OTHER RELATED STATE MECHANISMS

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825-X-2-.01 Criteria Standards.

(1) The Alabama Sickle Cell Oversight and Regulatory Commission was established by the Alabama State Legislature in the spring of 1996 to oversee the investment that the State makes in sickle cell services, education, screening, counseling, and research in Alabama. The composition of the Commission as defined by Act 96-727 includes: one representative from each of the seven Alabama Chapters of the Sickle Cell Disease Association of America; one representative from each of the two Comprehensive Sickle Cell Centers in the State; one representative of the Children's Hospital of Alabama; and two appointees of the Governor.

(2) One major goal of the Commission is to establish a set of criteria for entities receiving state support through the Education Trust Fund or through other related state mechanisms. Two entities worthy of funding serve an educational mission in our society, to all regions of the State and for all individuals with sickle cell conditions. These entities are: 1) the Alabama Chapters of the Sickle Cell Disease Association of America and 2) the Comprehensive Sickle Cell Centers in the State of Alabama. For the purposesof this document, the terms "sickle cell conditions" and "sickle hemoglobinopathy" are defined. The term "sickle cell condition" here refers to all individuals with sickle hemoglobinopathies and those with sickle cell trait. The term "sickle hemoglobinopathy" refers to all medically significant hemoglobinopathies, i.e., sickle hemoglobin inperson with clinical or laboratory abnormalities.

(3) The Commission recognizes three important points regarding these entities: 1) All current Alabama Chapters of the Sickle Cell Association of America (North Alabama Sickle Cell Foundation, North Central Alabama Sickle Cell Foundation, Sickle Cell Foundation of Greater Montgomery, Inc., SCDAA-Mobile Chapter, Tri-

County Sickle Cell Anemia Association, Southeast Alabama Sickle Cell Association, SCDAA-West Alabama) and UAB and USA Comprehensive Sickle Cell Centers are current, active participants in serving persons with sickle cell conditions; 2) There is a very important linkage between education-focused university-based Sickle Cell Centers and education-focused community-based Sickle Cell Chapters such that the Chapters are extended arms of the educational institutions for comprehensive services, and they enhance the accessibility of comprehensive sickle cell services to the residents of Alabama; 3) Unique pediatric health care facilities including the Children's Hospital of Alabama and the Women's and Children's Hospital in Mobile are formally affiliated with the Comprehensive Sickle Cell Centers and are currently active and valid recipients of Educational Trust Funds.
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825-X-2-.02 Comprehensive Sickle Cell Centers.

I. A Comprehensive Sickle Cell Center will:

(a) Be a defined Center with chartered approval by the Board of Trustees of an academic institution in the state of Alabama. The academic institution must have a graduate School of Medicine certified by the Licensing Commission for Medical Education (LCME) of the American Medical Association and of the America Association of Medical Colleges. The Medical School curriculum should include training in the basic and the clinical sciences sufficient to offer the MD degree.

(b) Offer fully certified and accredited services for pediatric and adult individuals with sickle cell conditions. Since by federal mandate sickle cell conditions are diagnosed at birth and both children and adults suffer illness as a result of sickle cell conditions, the Center must support programs for both adult and pediatric patients. Existence and support of adult and pediatric programs must be evident by participation of pediatric and adult subspecialists in the Center and by equitable sharing of the State appropriations to the Center to support both pediatric and adult programs. Therefore, said School of Medicine must have an LCME-certified Department of Pediatrics with at least one full-time academicall yappointed pediatric hematologist who is eligible for or certified by the Sub-Boardof Hematology/Oncology of the American Board of Pediatrics. For adults, said school of medicine must have a Department of Medicine with a least one full-time academically appointed, Specialty Board eligible for

Certified Adult Hematologist. The said Department of Pediatrics must serve pediatric patients (newborn-18 yrs) in a pediatric academic health care facility which offers a full range of pediatric medical, surgical, and psychosocial subspecialty services. Such services should be equivalent to those offered at the Women’s and Children’s Hospital in Mobile or the Children’s Hospital of Alabama in Birmingham in 1998. If services required to meet these Center criteria occur at a health care facility, foundation or other site which is not an incorporated element of the Center’s academic institution; the facility, foundation or site which is formally affiliated by written, mutual agreement with the Center may be specifically named to receive State funds for its service with the Center, with the Sickle Cell Oversight Commissions’ approval.

(c) Demonstrate capability in and financial support of state-of-the-art basic science, clinical science, public health and health care delivery research initiatives which develop, apply and assess the impact of educational programs, novel treatments and even cure for medical problems of individuals with sickle cell conditions.

(d) Provide follow-up testing of special hemoglobin disorders in individuals of any age identified within Alabama. Laboratories completing this testing must 1) be approved by the Department of Health and Human Services; 2) be certified under the 1988 Clinical Laboratory Improvement Act; and 3) participate in College of American Pathologists’ hemoglobin proficiency testing program. Specifically through interaction with the Center’s accredited Pediatric and Medical Departments and for individuals in its service region, the Center will offer a complete clinical and hemoglobin testing follow-up of all sickle hemoglobin disorders identified by the state of Alabama Newborn Screening Program or the Screening Programs of the Alabama Chapters of the Sickle Cell Foundations.

(e) Provide counseling regarding prenatal diagnostic testing for individuals and the parents of individuals with sickle hemoglobinopathies and collaborate with Sickle Cell Foundations to offer laboratory support of Foundations’ efforts to provide counseling for individuals and parents of individuals of all ages with sickle cell trait.

(f) Offer medical referral and comprehensive clinical care to individuals of all ages with sickle cell conditions.

(g) Provide sickle cell condition-specific education and training of health professionals who serve or are in training to serve individuals with sickle cell conditions. Further, the Center will help develop sickle cell condition-specific education to individuals and the families of individuals with sickle cell conditions.

(h) Collaborate with the Alabama Chapters of the Sickle Cell Disease Association of America to extend provision of comprehensive care to individuals with sickle cell conditions to their community.

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825-X-2-.03 Sickle Cell Chapters.

(1) The Sickle Cell Chapters will provide:

(a) Education Programs. One of the most important functions of the community-based sickle cell organization is to educate all people in the state of Alabama about sickle cell conditions and disease. Educational programs are designed to inform the general public and the at-risk population about sickle cell conditions; inform medical and social service providers about the needs of patients; office educational programs to the general public, affected families, medical and social service providers, employers and employment agencies.

(b) Screening Program. The second most important function of the community-based sickle cell organization is to screen the public in the state of Alabama for sickle cell conditions. All community-based sickle cell organizations must provide testing services that screen for any sickle cell condition. To carry out the screening program, all community-based sickle cell organizations must have trained, qualified person or entities (laboratories or organizations) to do the laboratory work.

(c) Counseling Service for Individuals Diagnosed with Sickle Cell Condition Disease. The third most important function is to counsel individuals with sickle cell condition or disease in the state of Alabama. To carry out the counseling program, all the community-based sickle cell organizations must have trained, qualified persons or entities to do the work.

(d) An Individual Must:

1. Have a bachelor’s degree in a natural or social science. Counselor currently employed must obtain the degree within the four years following the approval and ratification of this document by the Alabama Legislature.

2. Have training and certification in counseling.

(e) An Organization Must:

1. Be an affiliate member of the Sickle Cell Disease Association of America. The Sickle Cell Disease Association of America is the only known and identified governing parent organization. All community-based sickle cell organizations should be affiliate members.

2. Be a member organization of the Sickle Cell Disease Association of America, Alabama State Chapter.

(2) Linking Services: Link Individuals with sickle cell conditions or disease with primary health care providers in the community and the Sickle Cell Comprehensive Centers in the State of Alabama.

(3) Client Support Services provide services that enrich the lives of individuals with sickle cell condition or disease. All the chapters will provide support services for individuals and families affected by a sickle condition or disease. These services include pharmacy and physician referrals and other psychosocial support.

(4) Collaborate with the Comprehensive Sickle Cell Centers to provide comprehensive care for individuals with sickle cell conditions or disease.

(a) Be formally affiliated with a Comprehensive Sickle Cell Center. There are many medical complications associated with a sickle cell condition or disease. Comprehensive medical care is often essential to the well-being of a person with sickle cell condition or disease. The services offered at the Comprehensive Sickle Cell Center are not otherwise available in community hospitals. Programmatic linkages between community-based organizations and Centers enhance resource availability and continuity of care.

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825-X-2-.04 Complaint Process.

Introduction

1. Statutory Authority - In accordance with Section 22-10B-3(b) of the Code of Ala. 1975, the procedures in this section are intended to address complaints regarding service and management of statewide programs and address any other discrepancies brought to the attention of the Alabama Sickle Cell Oversight and Regulatory Commission ("ASCORC").

2. Exemption - Anyone providing direct medical care and/or functioning as a licensed physician is exempt from the procedures set forth in this section. Complaints concerning medical care and/or licensed physicians should be directed to the Alabama Board of Medical Examiners and Medical Licensure Commission.

3. Definitions

   a. Complainee: any individual or entity against whom a Complaint is submitted. This individual or entity must be regulated by the ASCORC pursuant to 825-X-2-.01(3) for these procedures to apply.
   b. Complainant: individual/entity submitting the Complaint.
   c. Services provided: any services performed as enumerated in Title 22-10B-5.[1] See 825-X-2-.03 for further discussion of these services.

Complaint Procedures

I. **Part One**

1. To file a Complaint that a Complainee has failed to provide services pursuant to Title 22-10B-5, Complainants shall follow the Complainee' s established complaint procedures. Complaints must be submitted within ninety (90) days of the alleged occurrence.

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[1] The sickle cell services shall include all of the following:-

1. Public and professional health education which shall be provided by persons specially trained for the task.
2. Screening of all newborns within a designated area for sickle cell disease by accurate laboratory techniques.
3. Genetic counseling and decision-making counseling which shall be offered to all parents of infants who are affected with Sickle Cell Disease and to those parents and patients at risk of having other children affected with this disease.
4. Medical referral and follow-up which shall consist of a prompt definitive diagnosis of patients found to have medically significant hemoglobin and the medical management of painful episodes,

infections, and other complications which shall be provided by physicians and other medical professionals.
5. Psychosocial support services which shall be provided to help patients affected with Sickle Cell Disease to live a happy and successful life.

2. If the Complainee does not have established complaint procedures, then the Complainant shall submit a written (signed) or videoed complaint to the Complainee alleging that the Complainee has failed to provide services in accordance with Title 22-10B-5. Complaints must be submitted within ninety (90) days of the alleged occurrence.

3. The Complainee shall investigate and make a final determination concerning the Complaint. The Complainee's final decision must be in writing and provided to the Complainant.

4. A copy of the Complaint and Complaninee's decision must be kept by the Complainee.

5. If the Complainant disagrees with the Complainee's determination, then the Complainant shall proceed to Part Two.

II. Part Two

1. Upon (a) receipt of a written (signed) or videoed Complaint to the ASCORC alleging that a community-based organization or any individual operating within the community-based organization regulated by ASCORC pursuant to 825-X-2-.01(3) has failed to provide services in accordance with Title 22-10B-5, and (b) verification that the Complaint has been presented to the Complainee and action was taken, the Executive Director of the ASCORC shall perform a preliminary review to determine if there is merit and sufficient evidence to warrant formal proceedings. Complaints must be submitted to ASCORC within thirty (30) days after the Complainee's final decision.

2. If the Executive Director and the ASCORC legal counsel determine that the Complaint may be meritorious and that sufficient evidence exists to warrant proceedings, the Complaint will be given to the investigative committee for further action. The investigative committee shall be formed pursuant to 825-X-l-.04 and will consist of one (1) ASCORC member, one (1) ASCORC counsel, and the Executive Director.

  a. When ASCORC receives a Complaint against a Complainee, ASCORC or its designee shall provide the Complainee with the allegations. The Complainee may submit to the Executive Director a written or videoed response and any supporting documentation.

  b. The investigative committee shall review the Complaint and other information submitted to determine if further investigation is warranted.

3. If further investigation is warranted, an investigator may be retained. The investigator shall work under the direction of the Executive Director to conduct further investigation.

4. At the conclusion of the investigation, the investigator shall submit an investigative report to be reviewed by the investigative committee, which has the authority to act on the report.

    a. The investigative committee shall send written notification to the Complainant and Complainee of any action it decides to take in response to the investigative report.
    b. If the investigative committee determines that the Complaint does not present a violation or is meritless, the Complaint shall be brought to ASCORC for dismissal without any further action.
    c. The Executive Director shall notify the Complainant and the Complainee that the investigation has been closed.

5. Following the investigation, if the Complaint requires further action, ASCORC or its authorized designee shall have the power to act on the report of the investigation as follows:

    a. Resolve the issue without a formal hearing (settlement),
    b. Institute a corrective plan of action, or
    c. Commence formal disciplinary proceedings with a hearing.

6. If the program remains noncompliant, ASCORC reserves the right to recommend reallocation of funding consistent with legislative intent pursuant to Section 22-10B-4 of the Code of Ala. 1975.
Author: Sara Rogan, Assistant Attorney General
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