

**NEW YORK STATE DEPARTMENT OF HEALTH**  
**CHILDREN WITH SPECIAL HEALTH CARE NEEDS PROGRAM**  
**WADSWORTH CENTER NEWBORN SCREENING PROGRAM**

**Criteria for Approval of Cystic Fibrosis Specialty Centers**

A Cystic Fibrosis (CF) Center is defined as an Article 28 general hospital that has at least one cystic fibrosis specialist. In addition to meeting the requirements specified for a general hospital in New York Codes, Rules and Regulations (NYCRR), Title 10, Part 405, a Cystic Fibrosis Center will meet the criteria specified below. If the Cystic Fibrosis Center will operate at more than one location, each sub site must be identified.<sup>1</sup>

**I. Hospital Administration**

Administration shall be responsible for:

- general operation of the center in accordance with written policies and procedures;
- employment or availability of qualified personnel, who maintain privileges at the hospital;
- compiling of statistical data, and review and revision of reporting systems and data collection;
- providing an annual update of all changes in personnel;

**II. Specialty Center Facilities**

Specialty Center facilities must include:

- inpatient and outpatient facilities available according to the needs of the individual patient;
- dedicated pediatric inpatient beds, neonatal intensive care unit as part of a level III perinatal program<sup>2</sup> and pediatric intensive care unit<sup>3</sup>;
- onsite facilities for standard clinical-pathological studies, radiological studies (i.e. X-rays, sonogram, CT, MRI) electrocardiogram studies, electroencephalogram studies and nuclear medicine studies;
- respiratory care department, with respiratory therapy available 24 hours a day, 7 days a week. Services would also include the ability to do pulmonary function tests, including ability to measure lung volumes in pediatric patients; and
- laboratory capability for all necessary studies as specified by the New York State Newborn Screening Program and the Wadsworth Laboratories.

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<sup>1</sup> The Permanent Facility Indicator (PFI) will identify the Cystic Fibrosis Center in the application. If the Cystic Fibrosis Center will operate at more than one location, each sub site must be specified by address and PFI number in the application. Each sub site will: a) be on the operating certificate of the Article 28 facility that is the main site; b) be identified by a PFI number; c) have physician specialists that have admitting privileges to the main site; and d) assure access to all services at the main site specified in these criteria.

<sup>2</sup> If the hospital does not provide maternity services, then a neonatal intensive care unit is not required.

<sup>3</sup> If the hospital does not have a pediatric intensive care unit (PICU), then a protocol must be described for emergent care, appropriate pediatric transport, and continuity of CF care.

In addition to standard clinical studies the laboratory shall have the capability to perform sweat tests by quantitative pilocarpine ionophoresis (in accordance with the NCCLS document) onsite and the following other core tests either onsite or by referral to another New York State approved laboratory:

1. Bacteriology
2. Blood chemistries
3. Arterial blood gases

### **III. Specialty Center Personnel**

#### **A. Core Personnel**

The core personnel consist of a medical director and any additional cystic fibrosis specialist.

##### **A.1. Medical Director, Cystic Fibrosis Center**

The medical director shall:

- be a cystic fibrosis specialist. A cystic fibrosis specialist is defined as either a board certified/eligible pediatric pulmonologist, pediatric gastroenterologist, or a board certified pediatrician with at least 5 years experience post-residency treating children with cystic fibrosis.
- assure that all children referred to the center are seen by the director or another cystic fibrosis specialist.

##### **A.2. Cystic Fibrosis Specialist**

The Cystic fibrosis specialist will assure:

- each child referred to the center receives an initial comprehensive evaluation, on an inpatient or outpatient basis, as indicated. The comprehensive evaluation includes a medical, psychological and social history, physical examination and appropriate diagnostic studies;
- appropriate treatment of the child is initiated, and assure the development and implementation of a plan for ongoing management with parental involvement;
- supportive services are in place to assist families with identifying resources and applying for benefit programs related to the financial aspects of care, education about the disorder and training about self-care for patients and their families;
- the child has a primary care provider;
- adequate and prompt reports on clinical evaluations, recommendations for treatment and follow-up and other necessary records are provided to referring physicians and, when requested, to the screening laboratory;
- guidance is provided for transitioning to adult care; and
- appropriate evaluation for patients already under treatment at the time of referral.

**B. Other Core Personnel**

The following personnel shall be available onsite for consultation:

- Medical Social Worker;
- Registered Dietician or Certified Dietician/Nutritionist;
- Licensed Respiratory Therapist;
- Registered Nurse Coordinator; and
- Laboratory Director who meets the qualifications specified in Part 19 Clinical Laboratory Directors, Section 19.2-19.4, Title 10, Official Compilation of Codes, Rules and Regulations of the State of New York. The Laboratory Director's Certificate of Qualification as issued by the NYS Clinical Laboratory Evaluation Program (CLEP) must include:
  1. Bacteriology
  2. Clinical Chemistry
  3. Blood pH and Gases

**C. Additional Personnel**

Consultation shall be available onsite or by referral in all specialties related to the care of the patient, including:

- board certified/eligible clinical geneticist
- genetic counselor who is board certified or an active candidate for certification;
- board certified/eligible pediatric pulmonologist;
- board certified/eligible pediatric gastroenterologist;
- recognized developmental specialist (a board certified/eligible developmental pediatrician, a board certified/eligible pediatric neurologist, or a licensed psychologist);
- board certified/eligible pediatric radiologist;
- board certified/eligible specialist in nuclear medicine;
- board certified/eligible pediatric urologist;
- board certified/eligible pediatric surgeon;
- board certified/eligible pediatric otorhinolaryngologist;
- board certified/eligible pediatric allergist/immunologist;
- board certified/eligible pediatric cardiologist;
- board certified/eligible pediatric endocrinologist; and
- board certified/eligible pediatric infectious diseases specialist.

Reference: Clinical Practice Guidelines for Cystic Fibrosis.  
Cystic Fibrosis Foundation, Bethesda, Maryland, 1997.