

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

**Criteria for Approval of Endocrine Specialty Centers**  
**(Includes Congenital Hypothyroidism, Congenital Adrenal Hyperplasia and Diabetes)**

An Endocrine Center is defined as an Article 28 general hospital that has at least one board certified/eligible pediatric endocrinologist. In addition to meeting the requirements specified for a general hospital in New York Codes, Rules and Regulations (NYCRR), Title 10, Part 405, an Endocrine Center will meet the criteria specified below. The center is able to treat, but is not restricted to, congenital hypothyroidism, congenital adrenal hyperplasia, and diabetes<sup>1</sup>. If the Endocrine Center will operate at more than one location, each sub site must be identified.<sup>2</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>3</sup>, and pediatric intensive care unit<sup>4</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;
- laboratory capability for all necessary core studies either onsite or by referral to another New York State approved laboratory as specified by the New York State Newborn Screening Program and the Wadsworth Laboratories.

---

<sup>1</sup> A Diabetes Only Specialty Center will be considered, when necessary, to serve the population needs in a specific geographic location.

<sup>2</sup>The Permanent Facility Indicator (PFI) will identify the Endocrine Center in the application. If the Endocrine 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; and 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 standards.

<sup>3</sup> If the hospital does not provide maternity services, then a neonatal intensive care unit is not required.

<sup>4</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 Endocrine care.

In addition to standard clinical studies, the laboratory shall have the capability to perform the following core tests either onsite or by referral to another New York State approved laboratory:

1. T4
2. Free T4
3. RT3 or TBG
4. RIA T3
5. TSH
6. Thyroid Antibodies
7. Thyroid uptake and scans using  $^{123}\text{I}$  preferably or Technetium
8. Plasma Serum Hormone Levels
9. ACTH Stimulation Tests
10. Plasma Renin Activity
11. Hemoglobin A1C
12. Serum ketones

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

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

The core personnel consist of a medical director and any additional board certified/eligible pediatric endocrinologist(s).

##### **A.1. Medical Director, Endocrine Center**

The medical director shall:

- be a board certified/eligible pediatric endocrinologist<sup>5</sup>; and
- assure that all children referred to the center are seen by the director or another board certified/eligible pediatric endocrinologist.

##### **A.2. Pediatric Endocrinologist**

The board certified/eligible pediatric endocrinologist 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;
- the child receives appropriate developmental evaluation and follow-up;
- 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;

---

<sup>5</sup> For a Diabetes Only Specialty Center, the medical director shall be a board certified/eligible pediatric endocrinologist, a board certified/eligible adult endocrinologist with appropriate experience treating children with diabetes or a board certified/eligible pediatrician with appropriate experience treating children with diabetes.

- 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 required by 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;
- 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:

Endocrinology  
Clinical Chemistry  
Hematology

**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;
- recognized developmental specialist (board certified/eligible developmental pediatrician, 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 plastic surgeon;
- board certified/eligible pediatric nephrologist;
- board certified/eligible pediatric neurologist;
- board certified/eligible pediatric cardiologist; and
- board certified/eligible pediatric ophthalmologist.

Reference: U.S. Newborn Screening System Guidelines II: Follow-up of Children, Diagnosis, Management, and Evaluation; Statement of the Council of Regional Networks for Genetic Services (CORN). The Journal of Pediatrics. October, 2000, 137:4.